JESSICA CLAIRE

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PROFESSIONAL SUMMARY

Well-qualified in Life Science Industry in various phases of Clinical Trial implementation and Subject Matter Expert responsible for Clinical Data Management applications like iMedidata, Cloud Admin, EDC Medidata Rave, Shared Investigator Platform, Oracle Clinical/TMS, Inform Architect. Skilled and pragmatic with strong attention to detail and methodical approach. Prepared to offer 11 years of experience to fast-paced position with room for advancement.

SKILLS

- Classic Rave, iMedidata, Cloud Admin EDC
- Oracle Clinical/TMS
- Inform Architect
- Shared Investigator Platform
- JIRA Systems
- SDTM
- Clinical GxP Process
- MS SQL Server, SQL Databases, C#

EDUCATION

Anna University Affiliated
04/2010

Bachelor of Engineering

CERTIFICATIONS

- Certified Rave Study Builder
- Certified in IT Service Management - EXIN ITILF ITIL®

WORK HISTORY

Upmc - Software Engineer Technical Lead
Aliquippa • 04/2016 - Current

- Primary Point of Contact for CDM applications like Oracle Clinical/TMS 4.5.1, EDC Medidata Rave, iMedidata, Cloud Admin, Shared Investigator Platform
- Provided clinical data management leadership within the study team to align on and drive data collection requirements for one or more complex clinical development projects from study start-up to study close-out
- Generated and maintained all required documentation including the development of specifications, coding, and validation efforts in support of eCRFs, database creation, coding setup, edit check procedures, import/export setup and processing, listings, and custom reports
- Performed major dictionary upgrades MedDRA and WHODrug in Oracle Clinical/TMS 4.5.6
- Elicited requirements and business needs and translated into functional specifications using business analysis tools and methodologies
- Interacts with clients and internal stakeholders, provide guidance to team members and execute projects through the course of coding, quality control, deployment, maintenance and support in order to deliver the project on time by ensuring maximum application uptime within the limits of SLAs
- Helped business in performing User Acceptance Testing during study migration and product releases
- Produced detailed and relevant GxP reports for use in making business decisions
- Enhanced project management skills reviewed internal systems and organized training plans to address areas in need of improvement
- Interviewed and observed clinical end users and business stakeholders to understand workflows, processes, business rules and systems in use
- Provided listings, missing page reports, discrepancy management reports
- Managed study team of 20 employees, overseeing hiring, training, and professional growth of employees

Cognizant Technologies Solutions, India - Clinical Data Management Lead
City • 11/2013 - 03/2016

- Primary point of contact of CDM systems like Oracle Clinical/TMS, Medidata Rave, JReview Rave, JIRA Systems, Data Management Plan
- Worked with programming to coordinate Study Data Tabulation Model maps
- Built and deployed plans, reports, validation procedures and entry processes for data management needs
- Development of reports using Business Objects
- Collected, reviewed and analyzed data from diverse departments for business needs integration for EDC system
- Upheld critical security standards when managing user access actions such as setting up and removing accounts, configuration of elearning
- Wrote work instruction manuals, data capture guidelines and standard operating procedures
- Saved $300K by implementing cost-saving initiatives that addressed long-standing problems
- Participated in risk assessment analysis for COTS products to minimize inherent liability in software releases
- Involved in change control process and supported client in post go live activities.

Cognizant Technologies Solutions, India - Senior EDC Programmer
City • 01/2013 - 10/2013

- Designed new/modify eCRF for clinical studies assigned in Oracle Clinical
- Programmed validation and derivation procedures for clinical studies assigned in Oracle Clinical
- Performed technical review of requirement specifications and provide review comments
- TMS and laboratory Data module Setup in Oracle Clinical
- Created listing as per requirement in SQL Developer and provide to TDM
- Responsible for all other study setup development activities. Track all activities performed daily in appropriate systems
- Performed the assigned activities to yield timely and high-Quality deliverable
- Ensured completeness and correctness of all training records and adherence to SOP's, iDMA SWP's, Productivity and Quality targets
- Contributed to Root cause analysis and Process improvements. Adhere to the communication and risk/issue escalation pathways
- Prepared good quality document relevant to the study development
- Analyzed the findings from QC and UAT and perform the update as required
- Organized knowledge sharing sessions and impart knowledge gathered from earlier studies.

Cognizant Technologies Solutions, India - EDC Programmer
City • 04/2011 - 12/2012

- Created business intelligence applications and tools to capture and exploit clients' requests data points and metrics.
- Worked with software development and testing team members to design and develop robust solutions to meet client requirements for functionality, scalability and performance.
- Handled both Inform and Clintrial studies using InForm Architect
- Used C# for form Design and XML scripts in Inform Architect
- Performed CTA activities on the assigned project in a timely and efficient manner
- Understand the client's requirements and review the trial functional specifications
- Presented Protocol Understanding slides of the study during Study Kick off Meeting in order to understand the client Specification for the study and also Interacting with the client team on trial timelines, standards and Technical study/program related issues (if any)
- Deployed the designed and developed study setup deliverables in client's environment and validated the same
- Performed Peer review before study setup activities are delivered to Data Manager/Client
- Involved in Post UAT changes for study setup activities
- Trained the team members on Sanofi Pasteur processes, tools, and clinical study as and when required
- Point of contact for the CTA subgroups and work with them on a day to day basis
- Managed the overall quality of deliverables including closure of all open QA issues
- Managed day to day activity including planning and work allocation
- Monitored daily deliverables and assured overall quality of deliverables and SLA adherence
- Performed defect analysis for the study and identify root cause for the issues and escalate it to Project Lead to incorporate the preventive actions across studies
- Attended the weekly/monthly status call with the client/offshore/DM
- Involved in effort estimation prior to development