Jessica Claire

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Summary

Dedicated and responsible Site Management Associate with over 8 years of experience in the clinical research industry including both CRO and site roles. Successful collaborator and competent at managing complex research projects in a fast-paced work environment. Well-organized in approaching problems to investigate causes and determine optimal solutions. Detailed understanding of organizational and regulatory expectations to drive performance. Proficient in Microsoft Office: Word, Excel, Outlook and PowerPoint as well as clinical trial softwares including Veeva Vault, PhlexView, eTMF3, PSO, CTMS and EDC systems..

Skills

- Guest services
- Inventory control procedures
- Merchandising expertise
- Loss prevention
- Cash register operations
- Product promotions

Experience

Site Management Associate II, 10/2021 - Current
Abbott Laboratories – Portsmouth, NH

- Achieve successful delivery of site start-up, in-house site management and close-out activities meeting internal and external client requirements
- Work closely with sites and study team members to coordinate the collection and review of essential documents in accordance with applicable Sponsor and ICON standard operating procedures (SOPs), ICH/GCP guidelines, and all applicable regulatory requirements
- Manage submission of Amended Protocol level documents (Protocol, IB, ICF, Patient Materials, Subject Recruitment Materials) and Continuing Review documents
- Proactively work with the site to answer queries including those related to vendor data
- Follow up on query aging and issuing queries as well as missing pages needed based on CRA/CMA review
- Performs and documents clinical data review and query creation, query resolution, offsite central monitoring contacts/visits and site management communications as outlined in the study plans (and/or other processes)
- Act as a liaison with clinical supply/service vendors and other functional area team members to meet project team goals
- Participate in the creation and maintenance of clinical project documents including, but not limited to Clinical Management Plans, monitoring Guidelines, Site Operations Manuals, Monitoring Visit Letter templates and Project
- Determine, tracks, and reviews milestones, tasks, timelines, and project hours for all the clinical activities for assigned projects, ensuring adherence to contract and budget
- Provide timely status reports for the clinical activities on assigned projects
- Ensure that all tasks meet Sponsor and PRA expectations, and are delivered in accordance with the contract, trial protocol, ICH/GCP and applicable SOPs
- Provide data as required for clinical operations performance metrics and project status metrics

Clinical Trial Specialist II, 03/2018 - 06/2020
Talis Biomedical – Concord, CA

- Perform investigator recruitment activities utilizing phone scripts, questionnaires, study site materials and other tools for use in evaluating investigative sites
- Perform essential document collection, review, maintenance and close-out activities, ensuring that sponsor and investigator obligations are being met and are in compliance with applicable local regulatory requirements and ICH/GCP guidelines
- Support investigators and site staff in fulfilling obligations with regard to local submissions according to local regulatory and Institution Review Board (IRB)/Independent Ethics Committee (IEC) requirements
- Perform study duties in adherence to the protocol, Clinical Management Plan (CMP), study processes, ICH-GCP and any other requirements stipulated on the study
- Follow up with sites for trial invoices and ensure CTMS is accurately updated to allow timely processing of Investigator Payments
- Determine, track, and review milestones, tasks, timelines, and project hours for all the clinical activities for assigned projects, ensuring adherence to contract and budget
- Act as a liaison with clinical supply/service vendors and other functional area team members to meet project team goals.

Clinical Trial Assistant, 01/2016 - 03/2018
Stanford School Of Medicine – Stanford, CA

- Assist the Clinical Project Managers (CPMs) and Clinical Research Associates (CRAs) with accurately updating and maintaining clinical systems that track site compliance and performance within project timelines
- Assist the clinical team in the preparation, handling, distribution, filing, and archiving of clinical documentation and reports according to the scope of work and standard operating procedures
- Assist with periodic review of the Trial Master Files for accuracy and completeness
- Assist CPMs with preparation, handling and distribution of clinical trial supplies and maintenance of tracking information
- Act as a central contact for the clinical team for designated project communications, correspondence and associated documentation.

Lead Clinical Research Coordinator, 11/2013 - 01/2016
Clinical Research Consultants – City, STATE

- Recruit, instruct and monitor patients as appropriate to specific study objectives
- Plan and coordinate the initiation of clinical trials in accordance with applicable study protocol, ICH-GCP,FDA,IRB,OHRP guidelines
- Maintain safety and confidentiality of research patients
- Collect, Process and shipp blood samples
- Managing drugs and supplies inventory
- Record and update data on clinical research forms and electronic data collection systems

Education and Training

Master's Degree: Environmental Science
University of Sciences Cadi Ayyad - Marrakech- Morocco

Bachelor's Degree: Biology
University of Sciences Cadi Ayyad - Marrakech-Morocco

Accomplishments

- ICH GCP E6 Training Program - Introduction & The Principles of ICH GCP
- ICH GCP Annual Refresher Subject Rights
- ICH GCP E6 Training Program - Sponsor: Monitoring, Auditing, and Noncompliance
- ICH GCP E6(R2) Training Program - Clinical Trial Protocol and Investigator's Brochure, Institutional Review Boards and Independent Ethics Committees
- GCP Serious Breach - How to Identify and Notify a Potential GCP Serious Breach
- Query Writing and Query Resolution
- Good Documentation Practices
- Configuration, Monitoring and Reporting of Protocol Deviations
- Managing Informed Consent Forms
- Clinical Trial Regulatory Documents, collection, review, approval and maintenance
- Guidance of the notification of serious breaches of GCP of clinical trial protocol
- Patient Safety and medical ethics
- Biomedical Research Basic course, CITI program
- Managing the Import and Export of Clinical Trial Supplies
- Distribution and Tracking of Safety Reports to Investigators and IRBIECs
- Management of Project Documents / Materials Translations