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Sr CRA1 at IQVIA

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Company: JobWebKenya

Location: Kenya

Category: business-and-financial-operations

Job Description

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IQVIA, formerly Quintiles and IMS Health, Inc.,is an American multinational company serving the combined industries of health information technology and clinical research. It is a provider of biopharmaceutical development and commercial outsourcing services, focused primarily on Phase I-IV clinical trials and associated laboratory and analytical services, including consulting services. It has a network of more than 58, employees in more than countries.As of , IQVIA was reported to be one of the world’s largest contract research organizations

Job Overview

Perform monitoring and site management work to ensure that sites are conducting the study(ies) and reporting study data as required by the study protocol, applicable regulations and guidelines, and sponsor requirements.

Essential Functions

Perform site monitoring visits (selection, initiation, monitoring and close-out visits) in accordance with contracted scope of work and Good Clinical Practice.

Work with sites to adapt, drive, and track subject recruitment plan in line with project needs to enhance predictability.

Administer protocol and related study training to assigned sites and establish regular lines of communication with sites to manage ongoing project expectations and issues.

Evaluate the quality and integrity of study site practices related to the proper conduct of the protocol and adherence to applicable regulations. Escalate quality issues as appropriate.

Manage the progress of assigned studies by tracking regulatory submissions and approvals, recruitment and enrollment, case report form (CRF) completion and submission, and data query generation and resolution. May support start-up phase.

Ensure copies/originals (as required) site documents are available for filing in the Trial Master File (TMF) and verify that the Investigator's Site File (ISF) is maintained in accordance with GCP and local regulatory requirements.

Create and maintain appropriate documentation regarding site management, monitoring visit findings and action plans by submitting regular visit reports, generating follow-up letters and other required study documentation.

Collaborate and liaise with study team members for project execution support as appropriate.

If applicable, may be accountable for supporting development of project subject recruitment plan on a per site basis.

If applicable, may be accountable for site financial management according to executed clinical trial agreement and retrieve invoices according to local requirement.

Qualifications

Bachelor's Degree Degree in scientific discipline or health care preferred. Req

Requires at least 2 years of year of on-site monitoring experience. Req

Equivalent combination of education, training and experience may be accepted in lieu of degree. Req

Good knowledge of, and skill in applying, applicable clinical research regulatory requirements.

i.e., Good Clinical Practice (GCP) and International Conference on Harmonization (ICH) guidelines.

Good therapeutic and protocol knowledge as provided in company training.

Computer skills including proficiency in use of Microsoft Word, Excel and PowerPoint and use of a laptop computer and iPhone and iPad (where applicable).

Written and verbal communication skills including good command of English language.

Organizational and problem-solving skills.

Effective time and financial management skills.

Ability to establish and maintain effective working relationships with coworkers, managers, and clients.

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