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Job Alert: Senior Clinical Research Associate at BeiGene, Australia

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The CRA performs monitoring activities related to initiation, conduct and timely completion of Oncology andPharma clinical trials within the country.

BeiGene

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Job Description

Purpose of the Job:

- The CRA performs monitoring activities related to initiation, conduct (recruitment, quality data collection) and timely completion of Oncology and Pharma clinical trials within the country.
- The CRA is responsible to deliver data within timelines and required quality standard, responsible for adherence to monitoring procedures in accordance with GCP and ICH, local regulations and SOPs.

Main Responsibilities:

- Conducts monitoring (pre-study, initiation, routine monitoring and closeout visit), if require
- Conducts co-monitoring visits, if required
- Ensures that study milestones for sites responsible are met as planned (i.e., study startup, recruitment, database analyses, closeout, etc.)
- Attends onboarding-, disease indication and project specific training and general CRA training as required
- Documents monitoring activities appropriately following ICH-GCP and BeiGene standards
- Conducts Quality Oversight Visits (QOV), as requested
- Completes monitoring visit/ QOV reports timely
- Assists with investigator/site identification
- Assists site to prepare Ethics Committee submissions
- Facilitates clinical trial site contract and budget negotiation
- Manages site queries and communications
- Assists in managing clinical trials, if required
- Establishes regular lines of communication with sites and COMs
- Provides protocol and related study training to assigned sites
- Evaluates the quality and integrity of site practices – escalating quality issues as appropriate

- Manages site performance by tracking regulatory submissions, recruitment, case report form (CRF) completion, and data query resolution
- Collaborates with CRA Group / CRM to ensure recruitment plans and execute contingency plans, as needed
- Performs additional task as assigned

Qualification Required

- Bachelor’s level degree or above in life sciences, pharmacy, nursing or medical
- Understands clinical trial processes with a thorough knowledge of ICH and associated regulatory guidelines
- Over 4 years of monitoring experience in the pharmaceutical or CRO industry
- Excellent communication and interpersonal skills
- Excellent organizational skills and ability to prioritize and multi-task
- Fluent in English (writing and speaking)
- A pplicant must have full Australian working rights to be considered.

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