

Senior Clinical Research Associate

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Company: BeiGene

Location: Israel

Category: other-general

BeiGene continues to grow at a rapid pace with challenging and exciting opportunities for experienced professionals. When considering candidates, we look for scientific and business professionals who are highly motivated, collaborative, and most importantly, share our passionate interest in fighting cancer.

General Description:

The Senior CRA executes clinical monitoring activities at clinical trial sites and monitors clinical trials in accordance with ICH guidelines and GCP, local regulations, and applicable SOPs.

May be assigned to CRA activities or start-up activities, depending on experience and project needs

Performs monitoring activities related to selection, initiation, conduct (recruitment, quality data collection) and timely completion of oncology/hematology clinical trials within the assigned region.

Identify gaps and areas for improvement and propose CAPA.

Supports start-up and provides local expertise.

The CRA is responsible for collaborating closely with the Regional Clinical Operations Manager to ensure study timelines are adhered to and required quality standards are maintained.

Senior CRA activities

Perform feasibility, site identification, selection and evaluation, preparing/supporting initial

list of sites and recruitment targets

Provides protocol and related study training to assigned sites.

Conducts monitoring (pre-study, initiation, routine monitoring and closeout) visit per monitoring plan and applicable SOPs

Conducts co-monitoring visits, if required

Completes monitoring visit reports in accordance with ICH-GCP, BeiGene standards and SOP

Manages sites and site performance by tracking regulatory submissions, recruitment, case report form (CRF) completion, and data query resolution

Establish regular lines of communication with sites and reports site progress, issues and proposed action to Clinical Operations

Ensure inspection readiness of the study and sites

Collaborates with Regional Clinical Operations Manager and clinical study sites to ensure timely delivery of study milestones (i.e., study startup, recruitment, database analyses, closeout, etc.)

Attends disease indication project specific training and general CRA training as required

Facilitate Study Oversight Visits (SOVs), site audits and/or inspections, as required

Evaluates the quality and integrity of site practices – escalating quality and/or GCP issues with Investigators and internal team as appropriate.

Anticipate and identify site issues; propose corrective and preventative actions; identify gaps and utilize opportunities. Constantly strive for operating excellence, question status-quo and promote innovation.

Computer Skills: Efficient in Microsoft Word, Excel, MS Project, MS PowerPoint and Outlook Other

Qualifications:

Understands clinical trial processes with a thorough knowledge of ICH and associated regulatory guidelines

Ideally 5+ years of (CRA) 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)

Travel up to 60%

Competencies:

Ethics- Treats people with respect; Inspires the trust of others; Works with integrity and ethically; Upholds organizational values.

Planning/Organizing - Prioritizes and plans work activities; Uses time efficiently.

Completes administrative tasks correctly and on time. Follows instructions and responds to management direction.

Communication Listens and gets clarification; Responds well to questions; Speaks clearly and persuasively in positive or negative situations. Writes clearly and informatively. Able to read and interpret written information.

Teamwork - Balances team and individual responsibilities; Gives and welcomes feedback; Contributes to building a positive team spirit; Puts success of team above own interests; Supports everyone's efforts to succeed. Contributes to building a positive team spirit; Shares expertise with others.

Adaptability – Able to adapt to changes in the work environment. Manages competing demands. Changes approach or method to best fit the situation. Able to deal with frequent change, delays, or unexpected events.

Technical Skills Assesses own strengths and development areas; Pursues training and opportunities for growth; Strives to continuously build knowledge and skills; Shares expertise with others.

Dependability Follows instructions, responds to management direction; Takes responsibility for own actions; Keeps commitments; Commits to long hours of work when necessary to reach goals; Completes tasks on time or notifies appropriate person with an alternate plan.

Quality Demonstrates accuracy and thoroughness; Looks for ways to improve and promote quality; Applies feedback to improve performance; Monitors own work to ensure quality.

Analytical - Synthesizes complex or diverse information; Collects and researches data; Uses intuition and experience to complement data.

Problem Solving - Identifies and resolves problems in a timely manner; Gathers and analyzes information skillfully.

Project Management - Communicates changes and progress; Completes projects on time and budget.

BeiGene Global Competencies

When we exhibit our values of Patients First, Collaborative Spirit, Bold Ingenuity and Driving Excellence, through our twelve global competencies below, we help get more affordable medicines to more patients around the world.

Fosters Teamwork

Provides and Solicits Honest and Actionable Feedback

Self-Awareness

Acts Inclusively

Demonstrates Initiative

Entrepreneurial Mindset

Continuous Learning

Embraces Change

Results-Oriented

Analytical Thinking/Data Analysis

Financial Excellence

Communicates with Clarity

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