

Argentina Jobs Expertini®

Clinical Research Associate II

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Company: BeiGene

Location: Argentina

Category: computer-and-mathematical

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.

PLEASE SUBMIT ALL RESUMES/CV'S IN ENGLISH FOR CONSIDERATION

Language Requirement: **Fluent English and Portuguese. Spanish is a plus.**

Preferred Experience: **Pharmaceutical/Biotech Industry, Hematology, Oncology**

Company Overview:

BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160) is a global, commercial-stage, research-based biotechnology company focused on molecularly targeted and immuno-oncology cancer therapeutics. With a team of over 10,000 employees across China, the United States (Cambridge, MA; Ridgefield Park, NJ; Emeryville, CA & San Mateo, CA), Switzerland, Australia and Brazil, BeiGene is advancing a pipeline consisting of novel oral small molecules and monoclonal antibodies for the treatment of cancer. BeiGene is working to create combination solutions aimed at having both a meaningful and lasting impact on cancer patients

General Description:

The CRA will assume the role of a primary CRA. The CRA will conduct site visits (i.e., PSSV, SIV, IMV, COV) and function as the site manager. The CRA is responsible to build and maintain relationships with key site personnel and ensure an effective line of communication. The CRA will also monitor data quality and patient safety through monitoring and site education. CRAs are to complete all aspects of the clinical monitoring

process in accordance with ICH-GCP guidelines, local regulations, and applicable SOPs.

Essential Functions:

- Perform and coordinate assigned aspects of the clinical monitoring process in accordance with GCPs and SOPs to assess the safety and efficacy of investigational products and/or medical devices
- Conduct site visits to determine protocol and regulatory compliance, and prepare required documentation
- Develop collaborative relationships with investigative sites, and study vendors
- Provide protocol and related study training to assigned clinical study sites
- Attend disease indication and/or project specific training, as required
- Maintain oversight of site performance by tracking metrics for enrollment, data entry into Case Report Forms (CRFs), protocol deviation trends, and overall site issues
- Serve as mentor/trainer for less experienced CRAs to assist with general and study-specific monitoring issues
- Communicate site performance to the Clinical Study Team (CST)
- Perform study-specific training with project team
- Perform Serious Adverse Event (SAE) reconciliation and work with study sites to resolve discrepancies
- Collaborates with CST and clinical study sites to ensure timely delivery of study milestones (i.e., study startup, recruitment, database analyses, closeout, etc.).
- Attend regional investigator meeting and site booster visits, as required
- Provide audit/inspection preparation support to clinical study sites and ensure quality issues or findings are followed to resolution, as needed
- Assist with other assigned clinical responsibilities within scope of role, as required

Minimum Requirements – Education and Experience:

BS/BA in a relevant scientific discipline and minimum of 2+ years of relevant Clinical Operations experience, and minimum of 1+ years of monitoring experience. Experience in global oncology trials preferred.

Other Qualifications:

Provides site level management for established protocols and portfolio under general supervision

Provides mentoring/support to CRAs for CRA related topics

Co-monitoring with CRAs and support site visits, as needed

Supervisory Responsibilities:

Travel: Up to 70%

Computer Skills:

- Efficient in Microsoft Word, Excel, PowerPoint and Outlook
- Familiar with industry CTMS and data management systems

#LI-Remote

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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