Our Client is a research driven and global acting biopharmaceutical company with strong focus on therapeutical areas of Hematology-Oncology and Immunology.

We are searching as soon as possible for a highly motivated

Clinical Research Associate (m/w/d)

Standort: Raum München
Kennziffer: 26221

Your tasks

The primary responsibilities of this position is to conduct routine site monitoring visits and participate in site selection, site initiation and study closure activities. This person will ensure that the clinical trial is being conducted according to the approved protocol, amendments and in compliance with Good Clinical Practice (GCP), Company SOPs, and all applicable regulatory requirements

- Responsible for evaluation, initiation, monitoring, close-out and other tasks associated with the management of clinical sites. Ensure the conduct of all clinical studies is in accordance with Good Clinical Practices, International Harmonization Guideline, and appropriate Standard Operating Procedures (SOP)
- Serve as primary contact for Clinical Research Organizations/ vendors, Investigators and study coordinators for study related questions
- In conjunction with study team, support feasibility and site selection process for clinical studies
- Supports country submissions and country requests as needed
- Assist and support development and review of clinical protocols, informed consent forms, or other study-related clinical documents (e.g. Case Report Forms, Source Documents, Monitoring Plan, Data Management Plan, Project Management Plan, etc.)
- Manage patient recruitment strategies to increase patient randomization into the trial (eg investigator and research nurse meetings, update newsletters, advertising, targeted letters...)
- Review all Adverse Events/Serious Adverse Events and ensure appropriate documentation is in place and any other safety issues are addressed and communicated
- Assist and support data validation and data cleaning procedures to ensure timelines are met
- Order and coordinate study supplies for clinical studies
- Develop and maintain tracking tools to support management of clinical studies
- Plan and participate in Investigator meetings and Clinical Research Associate trainings

Your qualifications

- Position requires Bachelor or nurse degree, preferably in the Life Sciences
- Minimum of 2+ years of experience in the pharmaceutical / biotechnology industry or CRO as a Clinical Research Associate from study start-up to database lock
- Strong Oncology monitoring experience in phase 1-3 pharmaceutical/ biotechnology clinical trials
- Possess good understanding of ICH guidelines, Good Clinical Practices (GCP), PhRMA code, FDA CFR, clinical research ethics, patient privacy laws, and other relevant, country regulatory requirements
- Good knowledge of concepts of clinical research and drug development
- Strong working knowledge of Electronic Data Capture, Interactive Voice/Web Response System and Clinical Trial Management System
- Ability to handle and prioritize multiple studies and projects
- Ability to work effectively in a team/matrix environment
- Ability to understand technical, scientific and medical information
- Demonstrated strengths in planning, organizational, project management, analytical skills, oral and written communication, time management, conflict management, problem solving, attention to
- detail, and interpersonal skills
- Fluent in German and English, oral and written
- Ability to travel 50% of working time or more

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Die professionelle, diskrete und transparente Betreuung unserer Kandidaten während des gesamten Bewerbungsprozesses steht dabei für uns im Mittelpunkt.

Ihr Ansprechpartner
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