CareerCross by JAC Recruitment

Senior Clinical Research Associate （BioPharma） Development Ope…

> アストラゼネカ株式会社での募集です。 臨床開発モニターのご経験のある方は歓迎で…

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
アストラゼネカ株式会社

Job ID
1488573

Industry
Pharmaceutical

Company Type
International Company

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
6 million yen ~ 9 million yen

Work Hours
09:00 〜 17:15

Holidays
【有給休暇】初年度 10日 1か月目から 【休日】完全週休二日制 年末年始 【有給休暇】※入社月により付与日数が異なります。詳…

Refreshed
January 31st, 2025 01:00

General Requirements

Career Level
Mid Career

Minimum English Level
Business Level

Minimum Japanese Level
Native

Minimum Education Level
Bachelor's Degree

Visa Status
Permission to work in Japan required

Job Description

【求人No NJB2194147】
【職務内容 / Job Description】
Monitor is responsible to ensure that the trial is conducted and documented properly by carrying out the following activities when relevant and necessary to the trial and the trial site in order to verify that:

The rights and well being of human subjects are protected.

The reported trial data are accurate complete and verifiable from source documents.
The conduct of the trial is in compliance with the currently approved protocol/amendment（s） with GCP and with applicable regulatory requirement（s）.

【Key Responsibilities】

・ Acting as the main line of communication between the sponsor and the investigator.
・ Communicate with Japan Study Leader and third party vendors as needed.
・ Conduct site selection activities for verifying adequate qualifications.
・ Manage and monitor the responsible sites and ensure their quality appropriately agreed cost spent and on a timely basis by conducting the followings;

Manage the contracts of clinical trial with the responsible site and ensure the compliance with regulations and company wide governance controls such as Ethical Interactions policy or company legal standard.
Input appropriate information in order to create clinical trial related documents （ex. CSP IND）.
Ensure a steady implementation of supplying clinical site with study materials.
Provide investigators and site staff with education and training regarding study specific procedures including EDC system.
Manage the patient recruitment status and request acceleration of patient recruitment for Investigators and site staff.
Conduct source data verification and ensure data quality to collect appropriate clinical study data.
If necessary support sites to ensure sites understand and resolve data queries in a timely manner.
Ensure that essential documents and source data are appropriately stored in a clinical site.
Produce monitoring activity reports appropriately and in a timely manner.
Confirm and ensure status of GCP/ICH guidelines CSP and AZ policy compliance.
Report critical and/or serious issues relating to site management to the study team and line manager in a timely manner.

・ Ensure input the latest site related information in IMPACT at appropriate timing.
・ Participate in house and/or external clinical trial related meeting （ex. Study team meeting CRA’s meeting Investigators’ meeting） including the preparations.
・ Cooperate with site audit in liaison with QA and a site inspection by regulatory authority.
・ Cooperate with resolving the result of SAE reconciliation.
・ Ensure inspection ready TMF regarding site related documents.
In addition to above Senior CRA also is to
・ Lead a certain number of CRAs （incl. CRO CRAs） to in terms of information management and communication related to site management in study team to keep monitoring quality.
・ Taking some tasks delegated by Study Leaders if agreed.
・ Contribute to the development of Clinical Operations Japan by joining some projects or initiatives e.g. Process Ownership responsibilities CRA training.
・ Mentor CRAs on monitoring and internal procedures.

Required Skills

■経験 / Experience

＜必須 / Mandatory＞

・ At least 3 years of CRA experience.
・ Demonstrated leadership capability in a team environment successfully.
・ Negotiated some complicated issues and/or requirements with site staff.
・ Team oriented and flexible; ability to respond quickly to shifting demands and opportunities

＜歓迎 / Nice to have＞

・ Preferred experience to collaborate with external partners.
・ Performed monitoring activities from qualification visit to closure visit as a CRA.

■Education

＜必須 / Mandatory＞

・ Bachelor’s degree （or equivalent） preferably in biological science or discipline associated with clinical research

■能力 / Skills and capabilities

＜必須 / Mandatory＞

・ Communication skill
・ Negotiation skill
・ Spirit of inquiry
・ Ability to manage for delivering the clinical study data.
・ Ability to plan effective monitoring activity
・ Ability to build and manage effective relationship with Investigators and site staff
・ Consistently exhibits Leadership capability as below:
・ Drives Accountability focuses on delivery/results; holds self accountable: Stretches and challenges self to meet or exceed high standards of behaviour and outcomes in line with AZ Values.
・ Works Collaboratively seeks diverse views: shares and seeks out diverse views incorporating them where appropriate in order to develop better proposals and creative solutions for the business
・ Demonstrate superior site monitoring and management skills at the site level covering more sites with multiple protocols compared to CRAs.
・ Examine issue signals and resolve them with appropriate resolution and timing.
・ Effective problem and conflict resolution skills especially for CRA/Site related issues. Collaborate with other function's

experts if needed.
・ Ability to share best practice and lessons learnt actively to improve quality and productivity of the wider monitoring team.
・ Excellent written and verbal communication skills as well as proven negotiation collaboration and interpersonal leadership skills
・ Influencing recognize the positive impact of own words actions and personal presentation on others （ex. Study team Other study teams Clinical Operation）. And also be able to present/explain an appropriate behavior to influence others.
・ The ability to build and manage effective relationship with CRO to keep monitoring quality.
・ Consistently exhibits Leadership capability as below
・Drives Accountability focuses on delivery/results; holds others accountable: communicated clear expectations of behavior and outcomes as well as why these standards matter. Holds others to account for delivering them
・Works Collaboratively encourages diverse views/thinking; creates environment in which diverse viewpoints are sought and encouraged both within beyond the team including with external partners.
・Strategic Leadership ・ clarifies complexity: thinks more broadly than their role （e.g. externally） and uses this insight to challenge and adapt current approaches in one’s area in an effort to simplify complexity and/or ensure alignment
・Acts Decisively ・ Takes Calculated Risk: Makes effective decisions despite uncertainty and/or incomplete information to drive business outcomes. Communicates learly to ensure alignment and empowers others with decision making authority as appropriate.

Company Description

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