



【R D】 Senior Clinical Research Associate (SCRA) 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...

募集職種

人材紹介会社

株式会社ジェイ エイ シー リクルートメント

採用企業名

アストラゼネカ株式会社

求人ID

1498070

業種

医薬品

会社の種類

外資系企業

雇用形態

正社員

勤務地

東京都 23区

給与

600万円 ~ 900万円

勤務時間

09:00 ~ 17:15

休日・休暇

【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...

更新日

2024年12月19日 12:01

応募必要条件

キャリアレベル

中途経験者レベル

英語レベル

ビジネス会話レベル

日本語レベル

ネイティブ

最終学歴

大学卒：学士号

現在のビザ

日本での就労許可が必要です

募集要項

【求人No NJB2096431】

【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.

スキル・資格

【経験 / Experience】

<必須 Mandatory : Required only for Senior role>

- 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

(Cumulativeでなく、随時担当しているような経験)

- 症例数 30前後
- 施設数 4以上
- 投薬例数 20以上

<歓迎 Nice to have: Preferred only for Senior role>

- Preferred experience to collaborate with external partners.
- Performed monitoring activities from qualification visit to closure visit as a CRA.
- 症例数 : 30前後
- 施設数 : 4以上
- 投薬例数 : 20以上

【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: Required for CRA>

- 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

<必須 Mandatory: Required for Senior role>

- 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 clearly to ensure alignment and empowers others with decision making authority as appropriate.

会社説明

医療用医薬品の開発、製造及び販売