

**CRA < FSP >**

臨床開発モニターのご経験のある方は歓迎です。

Job Information

Recruiter

JAC Recruitment Co., Ltd.

Hiring Company

非公開

Job ID

1588887

Industry

Contract Research Organization

Company Type

International Company

Job Type

Permanent Full-time

Location

Osaka Prefecture

Salary

5 million yen ~ 8 million yen

Work Hours

09:00 ~ 17:30

Holidays

詳細は求人ご紹介時にご案内いたします。

Refreshed

May 28th, 2026 02:00

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 NJB2297517】

Job Description

Responsible for all aspects of study site monitoring including routine monitoring and close out of clinical sites maintenance of study files conduct of pre study and initiation visits; liaise with vendors; and other duties as assigned

Assures the implementation of project plans for the clients as assigned at the client office where you will be dispatched

Responsible for all aspects of site management as prescribed in the project plans

General on Site Monitoring Responsibilities:

Ensure the study staff who will conduct the protocol have received the proper materials and instructions to safely enter patients into the study

Ensure the protection of study patients by verifying that informed consent procedures and protocol requirements are adhered to according to the applicable regulatory requirements

Ensure the integrity of the data submitted on Case Report Forms (CRFs) or other data collection tools by careful source document review. Monitor data for missing or implausible data

Ensure the resources of the Sponsor and Fortrea are spent wisely by performing the required monitoring tasks in an efficient manner according to SOPs and established guidelines including managing travel expenses in an economical fashion according to Fortrea travel policy

Prepare accurate and timely trip reports

Manage small projects under direction of a Project Manager/Director as assigned

Serve as lead monitor for a protocol or project and may assist in establishing monitoring plans and trip report review as assigned

Review progress of projects and initiate appropriate actions to achieve target objectives

Organize and make presentations at Investigator Meetings

Participate in the development of protocols and Case Report Forms as assigned

Participate in writing clinical trial reports as assigned

Interact with internal work groups to evaluate needs resources and timelines

Act as contact for clinical trial supplies and other supplies (vendors) as assigned

Responsible for all aspects of registry management as prescribed in the project plans

Undertake feasibility work when requested

Conduct report and follow up on Quality Control Visit (CQC) when requested

Recruitment of potential investigators preparation of EC submissions notifications to regulatory authorities translation of study related documentation organization of meetings and other tasks as instructed by supervisor as assigned

Negotiate study budget with potential investigators and assist the Fortrea legal department with statements of agreements as assigned

Complete process of Serious Adverse Event (SAE) reporting process production of reports narratives and follow up SAEs

Independently perform CRF review; query generation and resolution against established data review guidelines on Fortrea or clinical data management system assigned by management

Assist with training mentoring and development of new employees e.g. co monitoring

Co ordinate designated clinical projects as a Local Project Coordinator (with supervision if applicable) and may act as a local client contacts as assigned

Perform other duties as assigned by management

To be dispatched to the client for the project following the clients' working conditions (working hours/working places)

Required Skills

- ・ 学士資格 (薬学、医学、生物科学、看護などの分野尚可)
- ・ 臨床開発モニターとしての3年以上の経験 (医薬品、医療機器)
- ・ GCP (Good Clinical Practice) の知識
- ・ 英語を使用することに抵抗感の無い方

Company Description

ご紹介時にご案内いたします