■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
April 16th, 2026 17:03

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 venders; 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 lend 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