【800～1500万円】■Clinical Trial Manager（～Senior）

サイネオス・ヘルス・ジャパン株式会社での募集です。 臨床開発モニターのご経験の…

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
サイネオス・ヘルス・ジャパン株式会社

Job ID
1573535

Industry
Other (Medical, Pharmaceutical)

Company Type
International Company

Job Type
Permanent Full-time

Location
Osaka Prefecture

Salary
8 million yen ~ 15 million yen

Work Hours
09:00 ～ 18:00

Holidays
【有給休暇】初年度15日　4カ月目から 【休日】完全週休二日制 土 日 祝日 GW 夏季休暇 年末年始 毎週・曜日、毎週日曜日…

Refreshed
January 22nd, 2026 15:10

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 NJB2287016】
JOB SUMMARY
The Senior Clinical Trial Manager （ CTM） serves as the clinical functional lead accountable for the clinical monitoring/site management delivery of assigned tasks and project（s） as per scope. The Senior CTM may provide oversight and coordination of CTM（s） working across regions and/or countries to ensure clinical project and site deliverables are met. The position provides leadership mentoring and technical support

to the Clinical Operations team to ensure quality deliverables and achievement of milestones and financial goals. May provide administrative line management which includes oversight of training compliance performance development and career management of direct reports.
JOB RESPONSIBILITIES
As defined by scope may be responsible for team member clinical/site management project deliverables as the clinical functional team leader. Drives and manages the clinical and site management aspects of assigned project. May be a standalone lead or part of a regional or global clinical functional lead team. Reviews the study scope of work budget and protocol content and ensures the clinical project team （CRAs/CMAs/SMAs） is aware of the parameters. Escalates to the PM any clinical/site management deliverables （timeline quality and budget） at risk and any activities and requests which are out of contracted scope. Ensure alignment of clinical activities to budget including identification of out of scope activities.
・ Globally reviews Clinical Trial Management System （CTMS） Case Report Form （CRF） drug management safety Trial Master File （TMF） IVRS/IWRS enrollment Strategic Data Monitoring （SDM） and/or other dashboards to oversee site and project team conduct ensures timely entry of all operational aspects （required visits duration and frequency） according to plan and identifies risks to delivery or quality.
・ Coaches and mentors CTMs regarding functional clinical delivery evaluation of project risks and action implementation. Also sets priorities for the CTM team to complete and manage on a regional and site level.
・ Ensure quality of the clinical monitoring and site management deliverables within a project and/or program and maintain proper visibility of its progress by the use approved systems and / or tracking tools. May include the development of the Clinical Management Plan （CMP）/Site Management Plan （SMP）.
Understands the monitoring strategy required for the project and where required participates in the development of the project risk assessment plan. Is accountable for the clinical teams' understanding ongoing compliance and delivery according to the stated monitoring strategy CMP/SMP and risk plans
・ Reviews the content and quality of site monitoring documentation （site monitoring calls site visit reports site letters and pertinent correspondence） to ensure they represent site management activities and conduct. Ensures these deliverables are provided according to company and/or sponsor specifications including delivery deadlines
・ Maintains compliance on the project（s） for performance deliverables and associated KPIs.
・ Interact with the client and other functional departments related to clinical monitoring and site management activities and deliverables.
・ Collaborates with other functional areas to ensure site compliance and delivery according to protocol ICH/GCP and/or Good Pharmacoepidemiology Practices （GPP） and country regulations including medical monitoring Safety Quality Assurance （QA）. Ensures Inspection Readiness for Clinical Scope.
・ Ensures alignment of clinical activities to budget including identification of out of scope activities.
・ As required provides development and delivery of initial and ongoing training to the study team regarding protocol specifics Case Report Form （CRF） completion Sponsor Standard Operating Procedures （SOPs） clinical plans and guidelines data plans and timelines for the project. Plans and leads regular clinical project team calls to provide status updates ongoing training and accountability to deliverables.
・ As defined by scope may oversee the global project process and status of monitoring and data flow. Reviews status and trends at the study level holds CTM team accountable to manage at site and regional level for effective and timely Source Document Review （SDR） and/or Source Document Verification （SDV） and data flow reviewing status of site and project eCRF entry SDV triggered monitoring conduct query response and data cleanliness. Proactively collaborates with data management functional lead to plan towards data cut and lock deadlines. Develops and executes corrective action plans at study （global） level to address any issues.
・ May evaluate staff's competency to perform visits/site contact independently via sign off visits and Monitoring Evaluation Visits （MEVs） according to company standards and process.
・ May participate in business development activities including project clinical operations/site management strategy and budget input defense meetings and proposal development.
・ May be involved in Business Unit or corporate initiatives serving as a Clinical Operations SME.

Required Skills

Bachelor's degree or RN in a related field or equivalent combination of education training and experience
・ Prior line management experience preferred
Demonstrated ability to independently lead and align teams in the achievement of project milestones demonstrates accountability and ability to manage a global clinical operations team.
・ Knowledge of clinical project financial principles
・ Knowledge of Good Clinical Practice/ICH Guidelines and other applicable regulatory requirements
・ Must demonstrate good computer skills and be able to embrace new technologies
・ Excellent communication presentation and interpersonal skills among all internal and external customers
・ Subject Matter Expert of Clinical Operational process and delivery. Apply problem solving techniques to independently resolve complex issues and apply a risk management approach to identifying and mitigating potential threats to the successful conduct of a clinical research project
・ Demonstrates critical thinking to determine the cause and appropriate solution in the identification of issues. Able to present solutions and influence other stakeholders to accept those recommendations.
・ Moderate travel may be required approximately 20%
・ Demonstrates adaptability to change and serves as change agent to lead team members to adoption

Company Description

CSO（Contract Sales Organization）：製薬企業の営業及びマーケティング代行業務CRO（Contract Research Organization）：医薬品および医療機器に関わる臨床開発の受託事業