Clinical Research Associate / 臨床開発モニター

PSI CRO Japan株式会社での募集です。 臨床開発モニターのご経験のあ...

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
PSI CRO Japan株式会社

Job ID
1568541

Industry
Contract Research Organization

Company Type
International Company

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
6 million yen ~ 10 million yen

Work Hours
09:00 〜 18:00

Holidays
【有給休暇】初年度 最大10日（入社月によって異なる） 【休日】完全週休二日制 土 日 祝日 年末年始

Refreshed
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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 NJB2273386】
As a CRA you will work on the frontline of communication with project stakeholders ensuring timelines targets. You will have the opportunity to work on clinical studies in various therapeutic areas and indications while maintaining the highest quality standards in the industry. This function operates at site and country level and can be assigned to projects as monitor or lead monitor.

Join the PSI team and help drive innovation and excellence in advancing healthcare solutions.

You will:
Prepare conduct and reports site selection initiation routine monitoring and close out visits
Perform CRF review source document verification and query resolution
Be responsible for site communication and management
Act as a communication point between project teams and the site
Leads project team calls on a country level
Ensure that subject recruitment targets are timely defined communicated recorded and met and project timelines are followed at site level
Participate in feasibility research
Support regulatory team in preparing documents for study submissions
Prepare and participate in site audits and inspections
CRAとして、モニタリングおよび施設マネジメントの様々な業務を遂行し、正確で規制要件に従ったデータを確保し、被験者の権利と安全を確保します。さまざまな治療領域および適応症の臨床試験に取り組む機会があり、業界最高レベルの品質基準を維持します。PSI チームに参加し、ヘルスケアソリューションの革新と卓越性を推進してください。

・ 施設選定、契約手続き、モニタリング、終了手続き、及び報告書の作成
・ CRF レビュー、SDV、およびクエリ解決
・ 施設とのコミュニケーションおよび管理の責任
・ プロジェクトチームと施設間のコミュニケーション窓口
・ 施設ごとの目標症例数の協議・記録、および目標達成の確保、およびプロジェクトタイムラインの遵守
・ フィジビリティリ調査の遂行
・ 臨床試験関連書類の準備における薬事チームのサポート
・ 施設監査・当局査察の準備および参加

Required Skills

College/University degree in Life Sciences Pharmacy RN or an equivalent combination of education training experience
At least 3 years' site monitoring experience at a CRA II or equivalent qualification level in Japan
Experience in all types of monitoring visits in Phase II and/or III
Experience in feasibility assessment and study set up process is preferable
Therapeutic area experience in Oncology /Hematology /Gastroenterology （IBD） /Infectious Diseases /Neurology/Renal is a plus
Full working proficiency in Japanese and Intermediate English
PC skills to be able to work with MS Word Excel and PowerPoint
Ability to plan multitask and work in a dynamic team environment
Communication collaboration and problem solving skills
Ability to travel up to 30% to 40%

【必須要件】
・ 生命科学の学位、または同等の教育、訓練、経験
・ 日本において少なくとも2 年間の独立した施設モニタリング経験
・ Phase II またはIII の一連のモニタリング業務の経験
・ MS Office アプリケーションの使用習熟
・ 計画、マルチタスク、およびダイナミックなチーム環境での業務遂行能力
・ コミュニケーション、コラボレーション、および問題解決スキル
・ 日本語ですべての業務遂行能力を行えるレベルの高い日本語スキルおよび中級程度の英語スキル

【歓迎要件】
・ 腫瘍学/血液学/消化器病学（IBD）/感染症/神経学/腎臓の治療領域の経験

Company Description

PSI is a leading Contract Research Organization （CRO） with over 25 years of experience in the pharmaceutical industry. Originating from Switzerland PSI is a privately owned full service CRO with a global reach supporting clinical trials across multiple countries and continents. Our reputation for being highly selective about the projects we undertake highlights our commitment to delivering high quality timely services across a broad spectrum of therapeutic indications.In an industry where cost cutting and layoffs are common PSI stands out as a stable and secure workplace. Our dedication to stability is evident in our exceptionally high repeat and referral business rate and minimal staff turnover. Many of our colleagues have been with us for over 15 years contributing to our long standing traditions and history. Our expansion into Japan continues this legacy and we seek team members who will grow with us for the long term.At PSI we foster an environment where a diverse range of colleagues feel welcomed and valued. Our inclusive culture is a cornerstone of our success enabling us to attract and retain top talent globally.We are not just about conducting clinical trials; we are about building a community where every team member has the opportunity to thrive and contribute to groundbreaking advancements in the pharmaceutical industry.