

Study Startup Lead

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
1620404

Industry
Contract Research Organization

Company Type
International Company

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
6 million yen ~ 9 million yen

Work Hours
09:00 ~ 18:00

Holidays
【有給休暇】初年度 入社時最大10日（入社月によって異なる） 入社7ヶ月目には最低10日以上 【休日】完全週休二日制 土 日 ...

Refreshed
October 29th, 2026 18:25

General Requirements

Career Level
Mid Career

Minimum English Level
Business Level

Minimum Japanese Level
Native Level

Minimum Education Level
Bachelor's Degree

Visa Status
Permission to work in Japan required

Job Description

【求人No NJB2302347】
Take your career to the next level and be involved in leading the study startup processes in Japan. You will provide direct operational support to project teams from project start until activation and ensure that PSI clinical projects start smoothly and on time.

You will:

・Leads all study startup activities/processes with local project teams
・Support site identification and selection process
・Supports Project Management in developing and updating project/country startup and site activation timelines
・Supervises preparation and/or submission of the study dossiers to sites to the competent authorities IRBs/IECs etc.
・Leads/Supervises the development and negotiation of site contracts and budgets
・Reviews study specific translations
・Oversees and reports on the site activation progress of the clinical sites including identifying project specific issues and escalating to all functions concerned
・Ensures that project startup targets site activation timelines and contract deliverables are met pro actively addresses risks and supports risk mitigation.
・Ensures accurate tracking of startup events in CTMS and other applicable system（s） for the study.
・Coordinate initiatives for startup process improvement analyze best practices and challenges
・Trains project teams in startup processes
・Mentors department staff in the country
・Supports the development and update of manuals local instructions and user guides relevant to startup activities within the Country/Region
・Participates in process improvement initiatives testing and implementation of new study startup practices

Required Skills

・College/University degree or an equivalent combination of education training and experience
・Prior study and site startup experience in Japan
・Full working proficiency in English and Japanese
・Communication and organizational skills
・Ability to negotiate and build relationships at all levels

Company Description

PSI is a leading Contract Research Organization（CRO） with over 30 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.