【800～1200万円】Clinical Project Manager

臨床開発リーダー・臨床開発プロジェクトマネージャーのご経験のある方は歓迎です。

募集職種

人材紹介会社
株式会社ジェイ エイ シー リクルートメント

採用企業名
非公開

求人ID
1568367

業種
医薬品

会社の種類
外資系企業

雇用形態
正社員

勤務地
東京都 23区

給与
800万円 ~ 1200万円

休日・休暇
【有給休暇】最大20日（入社月に応じて変動あり） 初年度 10日 1か月目から 【休日】完全週休二日制 祝日 夏季休暇 年末年…

更新日
2025年12月11日 16:56

応募必要条件

キャリアレベル
中途経験者レベル

英語レベル
流暢

日本語レベル
ネイティブ

最終学歴
大学卒： 学士号

現在のビザ
日本での就労許可が必要です

募集要項

【求人No NJB2337946】
JOB SUMMARY
Primary Purpose / Regulatory Responsibilities:
・ Accountable for the delivery of patient centric studies from protocol design through to study report and archiving. These can be all types of study from First in Human to Phase 4 across all geographies and in all UCB theraputic areas including Gene Therapy.
・ Accountable for the effective interface and influential stakeholder management between UCB Phase 1 Units Clinical Research Organizations （CROs） and other vendors to ensure assigned studies are delivered according to contract specifications with high quality meeting all major milestones and to budget.

・ Lead study specific decision making and develop strategies for increasing study efficiencies.

MAJOR RESPONSIBILITIES
・ Accountable for the leadership and delivery of all assigned UCB sponsored clinical trials through effective internal and external team stakeholder management in a matrix organisation.
・ Responsible for operational updates issue/mitgations ensuring open transparent communication with team members line management and Clinical Strategic Partnering escalating within and outside the team as needed.
・ Demonstrate robust oversight of sponsor delegated activities by regularly reviewing CRO/Phase 1 Unit performance including TMF status through use of KPIs metrics and deliverables （such as SQV Impact） with a focus on trial subject safety data quality and critical activities that might delay the project or impact budget.
・ Responsible for Site Engagement strategies to support study recruitment at sites. Become familiar with the competitive landscapes; engage with Key Opinion Leaders （KOLs） investigational sites patient advocacy groups and other relevant organizations.

・ For assigned studies be the key internal clinical operations contact working closely with the respective PDL and other team members.
・ During start up articulate study scope goals and expectations of UCB to the CRO/Phase 1 Unit and ensure all relevant information that may impact the set up of the trial is highlighted and accounted for in the study planning.
・ Responsible for detailed planning of study timelines to enable timely access and prompt decision making for all data for Safety Monitoring/Data Monitoring Committees planned Interim Analyses final data reporting for Results Interpretation Meetings and final Clinical Study Report （CSR）.
・ Responsible to manage track and ensure accuracy of study budgets in UCB systems including the forecast and accrual information.
・ Work with CRO partners to define a study specific monitoring strategy. Review Monitoring Plans and CRA generated reports （as appropriate）.
・ Support any audit/inspection activities including audit/inspection readiness ensuring findings are appropriately addressed in a timely manner and overall compliance with regulations （eg ICH GCP） and applicable quality standards at all times.
・ Identify issues/gaps in processes and interfaces with other groups and departments and develop recommendations for resolution. Contribute to process improvement initiatives and share best practice experiences with line manager peers and Partner CROs.

スキル・資格

EDUCATION QUALIFICATION
Education Level : Bachelor's Degree

COMPETENCIES
Include specific skills behaviors and knowledge necessary to meet the objectives of the role
Technical:
Operational clinical project management experience （P1 4） including an understanding of the complexities of Global Clinical Development and Operations.
Ability and experience to manage study feasibility assessments vendor management study start up process different modalities of outsourcing data management risk based quality management.
Solid understanding of budgeting process budget follow up and forecasting.
Proficiency in the Microsoft office suite.

Leadership:
Ability to lead and maintain high performing multi disciplinary teams in a matrix environment.
A flexible proactive and adaptive management style.
Excellent time management and organizational skills.
Results and problem solving oriented. Presents “can do” attitude.
Effectively manage and influence all stakeholder relationships.
Excellent communication skills demonstrating clear and articulate verbal written and presentation skills with excellent command of the English language.
Ability to manage conflict and achieve consensus in a team.

会社説明

ご紹介時にご案内いたします