# 【R D】Clinical Site Lead （BioPharma） Site Management Monitori…

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## Job Information

**Recruiter**
JAC Recruitment Co., Ltd.

**Hiring Company**
アストラゼネカ株式会社

**Job ID**
1570295

**Industry**
Pharmaceutical

**Company Type**
International Company

**Job Type**
Permanent Full-time

**Location**
Tokyo - 23 Wards

**Salary**
6 million yen ~ 9 million yen

**Work Hours**
09:00 〜 17:15

**Holidays**
【有給休暇】初年度 10日 1か月目から 【休日】完全週休二日制 年末年始 【有給休暇】※入社月により付与日数が異なります。詳…

**Refreshed**
April 18th, 2026 05:00

## 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 NJB2345280】
【職務内容 / Job Description】
Clinical Site Lead （CSL） is a field based role within Site Management Monitoring （SMM） at AstraZeneca K.K. dedicated to supporting clinical trials within Japan. The CSL will be assigned to dedicated disease area and proactively drive site performance enhance site engagement and foster strong relationships with investigators and site staff based on enhancing knowledge at the specific disease area. The CSL will focus on driving recruitment performance and ensuring strong CRO

oversight without direct site management and monitoring responsibilities. This role will contribute to operational feasibility assessments and provide input on recruitment and retention strategies as well.

【Key Responsibilities】
・Planning: Contribute to the accurate site and recruitment plan
・Partnerships: Establish strategic partnership models and frameworks for deployment across key clinical sites and investigators.
・Communication: Maintain awareness of market activities policies trends technologies and information affecting the business to support the ongoing improvement of clinical recruitment efforts in line with company policies
・Strategic Input: Provide SMM input to clinical study documents including Clinical Study Protocol （CSP） Informed Consent Form （ICF） and Monitoring Plan.
・Performance Monitoring: Monitor study progress including country start up site activation and recruitment
・Risk Management: Track study performance and delivery risks and work alongside LST and GST to develop and implement mitigation plans.
・When the CSL is assigned to induvial clinical study having full responsibility for the site and study management from AZ KK the CSL will take following responsibilities.・
・Lead and manage all activities related to site management and monitoring including the following with agreed timelines and company standard quality in Japan.
・Plan and deliver a site selection strategy
・Plan patient recruitment strategy including SMO managements and following patient recruitment progress
・Lead and manage CRAs including CRO CRAs to deliver clinical study data
・Develop and manage risk mitigation plans and contingency plans to execute site managements and monitoring from site qualification to site close on time.・
・Lead and manage the quality of clinical study data.・
・Lead and manage queries and quality issues related to site management and monitoring together with CRAs.・
・Contribute to regulatory inspection in the area of site management and monitoring from study set up through conduct and inspection readiness.・
・Escalate issues related to site management and monitoring to an appropriate person and contribute to resolve.・
・Lead certain number of CRAs （incl. CRO CRAs） to in terms of information management and communication related to site management in study team to keep monitoring quality.・
・Contribute to the development of Development Operations Japan by joining some projects or initiatives e.g. Process Ownership responsibilities CRA training.・
・Contribute or encourage to innovate clinical trial environment with new technologies which AZ will implement cooperating with study sites and sites' staff.

## Required Skills

■経験 / Experience
＜必須 / Mandatory＞
・At least 3 years' experience in pharmaceutical industries or clinical research organization preferably in Clinical Operations （CRA Senior CRA）
・Demonstrated leadership capability in a team environment successfully.・
・Negotiated some complicated issues and/or requirements with site staff.
・Team oriented and flexible; ability to respond quickly to shifting demands and opportunities.

＜歓迎 / Nice to have＞
・Preferred experience to collaborate with external partners.
・Performed monitoring activities from qualification visit to closure visit as a CRA.

■Education
＜必須 / Mandatory＞
・Bachelor's degree in a related discipline preferably in life science or equivalent qualification

■能力 / Skills and capabilities
＜必須 / Mandatory＞
・Personal Effectiveness Drives Accountability in Others
・Learning Agility
・Financial Technology Process Competency
・Communication Teamwork ・ Influencing Collaboration Business Partnering
・Effective risk based thinking ・ Strategic thinking Problem Solving Critical Thinking Decision Making
・Deliver Priorities Results Impact ・ Project Management Recruitment/Retention Planning Action
・Act with Integrity high ethical standards

## Company Description

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