CareerCross by JAC Recruitment

【R D】 Data Management Leader （DML） R D Development Operations …

アストラゼネカ株式会社での募集です。 メディカルデータマネジメントのご経験のあ…

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
アストラゼネカ株式会社

Job ID
1511724

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
January 30th, 2025 06:00

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 NJB2269937】
■職務内容 / Job Description

Responsible to coordinate the Clinical Data Management （CDM） deliverables on assigned clinical projects and may be an expert on CDM processes standards and technologies such as EDC and other tools （PV提供用 安全性差分レポートツール etc.）. Member of the Study Team （ST） and the main point of contact for the Data Management （DM） vendor.

Responsible to ensure CDM deliverables follow standards and meet data quality. Maintains Business Continuity for CDM processes and standards including integrity of the clinical database for the relevant studies with ensuring AIR（always inspection readiness）.
Typical Accountabilities

Coordinate the CDM deliverables on assigned projects depending on the relevant model and DM Vendor. Takes accountability and serves as the first line of contact at the study level.
Communicates and collaborates effectively with all study level team members. Primary point of contact for DM vendor and provides guidance and supervision to Lead DM/DM Team Lead working on the study （CRO or in house）.
Oversight of the day to day operational aspects of CDM for assigned studies; Responsible to identify risks and collaborate with the DM Vendor to mitigate the risk.
Provide input into CDM related activities associated with regulatory inspections/audits for assigned RIST project（s）.
May provide input to the selection and use of software systems devices and vendors from the CDM perspective.
Drive adherence to AZ CDM standards and processes for data quality and consistency of data capturing for assigned studies.
Maintain an awareness of the external and internal models in order to participate in change initiatives and continuous improvement activities related to CDM operating models.
Demonstrates willingness to take on ad hoc activities consistent with current or experience in support of CDM and Japan DO/R D organization direction such as contributing the data driven decision making.

Required Skills

■応募資格（経験、資格等）/ Qualification （Experience Skill etc.）

＜必須 / Mandatory＞
Solid knowledge of CDM Database and experience in the Biotech/Pharma/CRO industry Demonstrated current understanding of Good Clinical Data Management Practices （GCDMP） and relevant regulatory requirements
Demonstrated experience of clinical databases different clinical data management systems and electronic data capture （EDC）
Demonstrate understanding and experience in query management process and reconciliation activities

＜歓迎 / Nice to have＞
Demonstrated knowledge of clinical and pharmaceutical drug development process
Demonstrated understanding of clinical data system design / development / validation and system interoperability.
Demonstrated ability to work effectively with external partners
Demonstrates professionalism diplomacy mutual respect and the ability to manage/value diversity and cultural differences and promote productivity through encouragement

【資格 / License】

＜必須 / Mandatory＞
Bachelor’s Degree

＜歓迎 / Nice to have＞
Certified Clinical Data Management

【能力 / Skill set】

＜必須 / Mandatory＞
Good communication and interpersonal skills including effective problem solving
Ability to work independently without close supervision
Excellent written and verbal communication skills
Ability to work in a global team environment
Excellent organizational and analytical skills and high attention to detail
Excellent knowledge of spoken and written English

＜歓迎 / Nice to have＞
State of the art understanding of database structures programming languages data standards （CDISC） and practices as they apply to CRF design database development data handling and reporting

【語学 / Language】

＜必須 / Mandatory＞
日本語 Japanese：ネイティブ

英語 English：英語 English： Business English （Achieve common understanding at the context level with customers）

【その他 / Others】

＜必須 / Mandatory＞
Computer proficiency

＜歓迎 / Nice to have＞
Knowledge of SQL VBA Python/R software BI tool（Spotfire Power BI） and RWD

Company Description

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