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...

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
アストラゼネカ株式会社

求人ID
1511724

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
600万円 ~ 900万円

勤務時間
09:00 ～ 17:15

休日・休暇
【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...

更新日
2025年01月16日 12:01

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
ビジネス会話レベル

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 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.

スキル・資格

■ 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

会社説明

医療用医薬品の開発、製造及び販売