



【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 2nd, 2025 08:00

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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