

【800 ~ 1800万円】Clinical Trial Physician

ブリストル・マイヤーズ スクイブ株式会社での募集です。 臨床開発リーダー・臨床...

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
ブリストル・マイヤーズ スクイブ株式会社

Job ID
1619884

Industry
Pharmaceutical

Company Type
International Company

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
8 million yen ~ 18 million yen

Work Hours
09:00 ~ 17:15

Holidays
【有給休暇】年次有給休暇は入社時から付与されます。 初年度:試用期間終了後1 ~ 10日（入社時期により異なる）/2年度目:13...

Refreshed
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General Requirements

Career Level
Mid Career

Minimum English Level
Business Level

Minimum Japanese Level
Native Level

Minimum Education Level
Bachelor's Degree

Visa Status
Permission to work in Japan required

Job Description

【求人No NJB2300128】
Position Summary

The Japan Clinical Trial Physician sits within Clinical Development which is dedicated to the effective design and execution of drug development. Clinical Trial Physician contributes and drives clinical development strategy design execution and interpretation of clinical trials closely working with Japan Clinical Leads and global clinical counterpart.

Duties/Responsibilities

Medical Monitoring

Conducts medical data review of trial data including eligibility review
Holds responsibility for site interactions in partnership with the Japan Clinical Lead or Clinical Scientist for medical questions and education（including safety management guidelines）
Holds responsibility for assessment of key safety related serious adverse events of R D clinical trials in partnership with Worldwide Patient Safety and oversees safety narratives
Collaborate with Japan Clinical Lead or Clinical Scientist and inputs into protocols providing medical strategic oversight in protocol development（input on inclusion/exclusion and other safety related clinical considerations）
Fulfills GCP and compliance obligations for clinical conduct and maintains all required training
The range of CTP's medical accountability/responsibility differs in global vs local studies. For global studies Japan CTP is assumed to assist global CTP as needed from local perspectives e.g. provide local medical related input resolve local medical related issues.
Japan CTP could be expected to take a primary CTP role for local initiated trials or program
Clinical Development Expertise Strategy

In collaboration with the Japan Program Development Team such as Clinical Lead designs and develops project/clinical plans and protocols with a strong strategic focus based on knowledge of asset/drug disease area and relevant science in order to meet regulatory and disease strategy targets
Provides oversight and medical accountability for a group of studies
Leads the analysis of benefit/risk for clinical development protocols and projects in a matrix team environment working with Japan TA
Partners with Japan the Japan Program Development Team such as Clinical Lead to support executional delivery of studies（e.g. enrollment review as well as adjudication for protocol violations significant non significant deviations etc.）
Identifies and builds relationships with principal investigators. Identifies and cultivates thought leaders in order to gain their inputs on emerging science in drug and biomarker research disease knowledge and design of clinical development studies and programs
Maintains a strong medical/scientific reputation within the disease area. Has in depth knowledge of etiology natural history diagnosis and treatment of the disorder. Holds strong expertise in the disease area by attending scientific conferences and ongoing review of the literature
Keeps abreast of development and regulatory issues related to other competitive or relevant compounds in development and how our portfolio fits into the competitive landscape
Provides ongoing medical education in partnership with collaborating Clinical Scientists to allow for protocol specific training supporting the study team investigators and others
Health Authority Interactions Publications

Contributes to and serves as medical point of expertise in key Health Authority interactions and advisory board meetings as Clinical Trial Physician
Authors/drafts clinical content for CSRs regulatory reports briefing books and submission documents to support closure clinical narratives reporting and filling of the study in partnership with TA such as Clinical Lead or Clinical Scientist

Required Skills

Key Competency Requirements:

Ability to deliver the outcomes under the ambiguity or complexity
Ability to partner with people at all levels of the organization
Ability for proactive proposal building and proactive action takings without detailed instructions
Ability to respond flexibly to the changing project/task priorities and work assignments.
Ability to influence and negotiate without specific authority.
Ability to take a risk and to manage it without jeopardizing quality and/or compliance
Ability to build action plans based on the organization vision
Acts to makes a balance between short term performance and long term vision.
Fluent in spoken and written English Japanese for business is preferred

Company Description

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