Global Clinical Operations- Study Start-Up CRA

Job ID
REQ-10032137

12月 04, 2024

China

摘要

监控与临床研究网站和临床试验参与相关的患者数据和学习相关信息。确保调查员遵守研究协议、法规要求和良好临床实践，并为数据验证计划提供投入。提供及时和准确的监测患者数据和研究相关信息，从源文件，研究记录和现场访问（如果适用）可以监控学习地点和审计设施的选择。

About the Role

Key Responsibilities：

- Supports country SSU strategy in close collaboration with SSO Study Start-Up Team Lead, SSO Study Start-Up Manager, SSO Feasibility Manager as well as SSO Site Partnership Manager
- Collaborates with SSO Study Start-Up Manager, SSO Study Start-Up Team Lead and global study team to ensure Study Start-Up timelines and deliverables are met according to country commitments

- Accountable for timely start-up activities from country allocation until site greenlight at assigned sites
- Conducts site selection visits, verifies site eligibility for a specific study
- Main contact for trial sites during site selection, study start-up and IRB/IEC and HA submission preparation
- Ensures that milestones (KPIs) and time schedule for study start-up are met as planned
- Facilitates the preparation and collection of site and country level documents
- Collects submission relevant site-specific documents (e.g., FD, CV, GCP certificates, DSL...) for all relevant site personnel within agreed timelines
- Supports SSU Manager in preparation of country-specific documents, e.g., ICF, patient facing materials, etc.
- Supports SSO Study Start-Up Manager and assigned sites in vendor set-up activities
- Prepare and finalize site specific documents for submission
- Negotiates investigator payments as needed
- Supports preparation of financial contracts between Novartis and investigational sites and investigators as needed
- Updates all systems until site Green Light on an ongoing basis
- Supports preparation of audits and inspections as applicable
- Supports reduction of formal site-specific IRB/IEC deficiencies

- Ensures timelines, accuracy, and quality of country and site TMF documents in study start-up to ensure TMF inspection readiness
- Ensures adherence to financial standards, prevailing legislation, ICH/GCP, IRB/IEC, Health Authority and SOP requirements
- Implements innovative and efficient processes which are in line with Novartis strategy

- Ensures sites are prepared for "Green Light" and is accountable to send the Green Light to SSU Manager for review and approval

Commitment to Diversity and Inclusion / EEO:

Novartis is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve.

Essential Requirements:

- A degree in scientific or health discipline, preferably with clinical operations experience (or, for United States: 4-year degree plus relevant, related healthcare experience)
- Fluent in both written and spoken English, local language as needed
- Minimum 3 years' experience in clinical operations in a monitoring / site management role

Desirable Requirements:

- Advanced understanding of all aspects of clinical drug development with particular emphasis on trial set-up, execution, and monitoring
- Central/in-house monitoring or field monitoring experience is desirable

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining

to achieve breakthroughs that change patients 'lives. Ready to create a brighter future together?

Benefits and Rewards: Go to Novartis career website to learn about all the ways we 'll help you thrive personally and professionally.

Accessibility and Accommodation:

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please tell your relevant request to our hiring managers.

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Benefits and Rewards: Read our handbook to learn about all the ways we 'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

部门
Development

Business Unit
Innovative Medicines

地点
China

站点
Beijing (Beijing)

Company / Legal Entity
CN06 (FCRS = CN006) Beijing Novartis Pharma Co., Ltd

Functional Area
Research & Development

Job Type
Full time

Employment Type
正式

Shift Work
No

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无障碍及便利 设 施

诺华 承 诺 与残障人士共事并 为 他 们 提供合理的便利 设 施。如果您由于健康状况或残障 在招聘 过程的任何 环 节 需要合理便利 设 施 或者 为 了履行 职 位的基本 职 能 请发 送 电 子 邮 件至 diversityandincl.china@novartis.com 告知您的需求和 联 系方式，并在 邮 件中附上您的 职 位申 请编

号。

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