

Clinical Project Manager

Job ID
REQ-10013675
Juli 11, 2024
Südkorea

Summary

- Contributes, with appropriate oversight, to all relevant aspects of local clinical trial(s) activities to deliver study outcomes within schedule, budget, quality/compliance and performance standards.
- May lead specific aspects of local clinical trial(s).
- Core member of the Clinical Trial Team, Contributes to operational excellence through process improvement and knowledge sharing and/or provide inputs to clinical development process.
- Applicable to Clinical Project Manager provides clinical and scientific support through all phases of a clinical study in compliance with Novartis processes, ICH GCP and regulatory requirements.
- This role applies the principles of clinical data review excellence and identifies clinical data insights to ensure data is scientifically plausible and to identify trends, signals and risks associated to trial endpoints and patient safety.
- The CPM is a core member of the Clinical Trial Team (CTT). In addition, the CPM supports/leads program level documents or activities as assigned.

About the Role

Internal Role Title: Clinical Project Manager

Location: Seoul, Korea #LI-Hybrid

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

Key Responsibilities:

- Contributes to all operational/clinical trial deliverables that are in scope of the specific JD, according to timelines, budget, operational procedures, quality /compliance and performance standards.
- Conduct/Contribute to study start-up activities such as overseeing protocol development, CRF development, Informed Consent Form development.
- Ensuring proper handling of all study conduct and close out activities including but not limited to site close out, final drug accountability and audit readiness of Trial Master File documentation (if in scope of the specific JD).
- Responsible for education, implementation and compliance to standards (SOPs) and best practices for clinical operations/clinical data review activities within assigned clinical trial(s) and within clinical program(s), including sharing lessons learned.

- Timely, efficient and quality execution of assigned trials and trial related activities within budget, and in compliance with quality standards.
- Proactive operational planning with effective contingency and risk mitigation plans.
- Adherence to Novartis policy and guidelines and external regulations
- Performing clinical data review and insights consistently and accurately which meets the Novartis quality standards, timelines, and is inspection ready.
- High quality contributions to study/ program level and/or submission documents (e.g. IDP, protocol, ICF, clinical sections of CTA).
- Strong leadership skills to be able to support management in team competency building, lead/contribute to local/global initiatives and best practice sharing across programs and/or departments
- Clearly demonstrates Novartis Values and Behaviors (i.e. Innovation, Quality, Collaboration, Performance, Courage and Integrity).

Essential Requirements:

- +7 years of relevant experience and being familiar with domestic clinical trial-related regulations and GCP
- Good understanding of the medical field and strategical managing skill on the local study with familiarity domestic regulations and global practices.
- Problem solving in ongoing competition and challenging situations

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Division

International

Business Unit

Innovative Medicines

Standort

Südkorea

Site

Seoul

Company / Legal Entity

KR01 (FCRS = KR001) Novartis Korea Limited

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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