NOVARTIS

Senior Clinical Project Manager

Job ID
REQ-10005828
Aug 02, 2024
Czech Republic

Summary

Location: Czech Republic, Prague #LI-Hybrid

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

The Senior Clinical Project Manager lead a global study team responsible for the planning and implementation of all operational aspects of scientifically and operationally complex studies from study concept to clinical study report/manuscript writing, according to timelines, budget, operational and quality standards.

About the Role

Key Responsibilities:

- Collaborate with colleague/customer team and Line Functions to establish realistic project timelines. Escalate any unresolved disagreements to higher management.
- Lead and manage a multidisciplinary Clinical Trial Team (CTT), ensuring effective planning, evaluation, and implementation of assigned clinical studies and programs.
- Organize and facilitate investigators meetings and internal meetings related to study execution and operational excellence.
- Interact with investigator sites and CRAs/CROs/vendors to ensure smooth study setup and conduct, monitor site performance, address protocol deviations, and resolve issues.
- Support compilation of study regulatory documents for submissions and assist with monitoring activities and communications with partners.
- Review site visit reports and monitor activities for quality control.
- Chip in to ongoing medical/scientific data quality review and coordinate data analysis and interpretation for first results.
- Assist in developing study protocols, treatment plans, informed consent forms, and other essential study documents.
- Contribute to clinical sections of regulatory documents and ensure approval from colleague/customer.
- Handle the writing or liaise with medical writing/narrative group to ensure completion of the Clinical Study Report.
- Set up and maintain the Trial Master File (TMF), Clinical Trial Management System (CTMS), and other required systems in collaboration with Clinical Operations Specialists.

Essential Requirements:

- Life Science degree or equivalent of education, training and experience

- Fluent English (oral and written)
- 10+ years of Clinical Operations experience with strong managerial experience in planning, driving, reporting and publishing clinical studies (interventional and non-interventional, early to late phase) in a pharmaceutical
- Confirmed ability to work independently, to lead a multidisciplinary cross-functional team in a complex matrix environment (including remote).
- Thorough knowledge of Good Clinical Practice, clinical study design, statistics, regulatory processes, and global clinical development process.

Benefits and rewards: Monthly pension contribution matching your individual contribution up to 3% of your gross monthly base salary; Risk Life Insurance (full cost covered by Novartis); 5-week holiday per year ; 4 paid sick days within one calendar year in case of absence due to sickness without a medical sickness report; Cafeteria employee benefit program – choice of benefits from Benefit Plus; Meal vouchers in amount of 105 CZK for each working day (full tax covered by company); MultiSport Card et al. Find out more about Novartis Business Services: https://www.novartis.cz/

Commitment to Diversity and Inclusion:

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

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? https://www.novartis.com/about/strategy/people-and-culture

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Division
Operations
Business Unit
CTS
Location
Czech Republic
Site
Prague
Company / Legal Entity
CZ02 (FCRS = CZ002) Novartis s.r.o
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work

No
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Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to di.cz@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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