

# Clinical Project Manager

Job ID

REQ-10005829

Mai 09, 2024

Tschechische Republik

## Zusammenfassung

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. As a Clinical Project Manager, you will be responsible for coordinating and managing all aspects of assigned clinical studies, from early phase to late phase. This includes both interventional and non-interventional studies, as well as other clinical services such as managed access programs, research collaborations, and digital solutions. Working under the lead of the Senior Clinical Project Manager, you will collaborate with a team of experts to plan and implement all operational aspects of the studies. From concept to reporting and manuscript writing, you will ensure that timelines, budgets, and quality standards are met, following required procedures. In addition to handling the studies, you will also play a crucial role in fostering ongoing and effective collaboration with colleagues, customers, and other line functions. You will track performance and quality aspects, ensuring that all stakeholders are satisfied with the services provided by CONEXTS.

## About the Role

### Key Responsibilities:

- Collaborate with colleagues, customers, and line functions to establish realistic project timelines. Escalate issues to higher-level management if no agreement can be reached.
- Lead and manage a multidisciplinary cross-functional Clinical Trial Team or support the Senior Clinical Project Manager in planning and implementing clinical studies and programs.
- Organize investigator meetings and internal meetings related to clinical study execution.
- Interact directly with investigator sites, CRAs, CROs, and vendors to ensure smooth study set-up and conduct, monitor site performance, address protocol deviations, and resolve issues.
- Assist in the compilation of regulatory documents for submissions to authorities and ethics committees.
- Review site visit reports and ensure quality control of monitoring activities.
- Contribute to ongoing medical/scientific quality review of study data and coordinate data analysis and interpretation for initial results.
- Contribute to the development of study protocols, amendments, informed consent forms, and other essential documents.
- Manage study budgets and provide input for clinical outsourcing specifications.
- Identify areas for process or technology improvements and participate in continuous improvement initiatives.

### Essential Requirements:

- Bachelor's degree or higher in life sciences or a related field, or equivalent combination of education, training, and experience.

- Approximately 8 years of experience in Global Clinical Operations, with managerial experience in designing, planning, executing, reporting, and publishing clinical studies, both interventional and non-interventional, across different phases.
- Proven ability to work independently in a complex matrix environment, including leading cross-functional teams.
- Strong project management skills.
- In-depth knowledge of Good Clinical Practice (GCP), clinical study design, statistics, regulatory processes, and the global clinical development process.
- Excellent spoken and written English.
- Excellent presentation and diplomacy skills, with the ability to negotiate and resolve conflicts.

**Desirable Requirements:**

- Ability to independently resolve issues and know when to escalate them
- Accountable and responsible in project and study management.

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**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.

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Abteilung

Operations

Business Unit

CTS

Ort

Tschechische Republik

Website

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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