MorphoSys' mission is to make exceptional, innovative biopharmaceuticals to improve the lives of patients suffering from serious diseases. Innovative technologies and smart development strategies are central to our approach. Success is created by our people, who focus on excellence in all they do, collaborate closely across disciplines. We all are driven by a desire to make the medicines of tomorrow a reality. Guided by mutual respect and trust, each member of the MorphoSys team is given the opportunity to develop and flourish within this exciting and inspiring environment. Join us in Planegg near Munich!

We would like to fill the following vacancy as soon as possible:

(Senior) Clinical Trial Manager (gn)

Your Responsibilities:

- Contributes to planning of global clinical trials and designs site management processes from study start-up to closure in collaboration with global CRO(s) and sponsor Clinical Trial Team (CTT) meeting the requirements of the protocol and MorphoSys standards
- Set-up of performance metrics to oversee and monitor the performance of CRO(s) and site activities in international clinical studies
- Participates in trial risk assessment and management activities; recognizes potential challenges within the protocol and operational aspects of the trial
- Serves as main sponsor contact to CRO site management team
- Participates in the CRO selection process and approves key CRO site management staff (e.g. Clinical Trial Managers, Lead Clinical Research Associates (CRAs) and CRAs)
- Maintains a strong knowledge of the protocol and study procedures to be able to answer operational questions from CRO
- Contributes to and reviews study plans and documents (e.g. Drug Handling Manual, trial-level Informed Consent Forms (ICFs))
- Approves country / site ICF customizations prepared by CRO(s) and oversees timely ICF implementation on global site level
- Reviews and approves CRO monitoring plan, monitoring visit report annotations and Investigator Site File templates prepared by CRO
- Develops and implements the sponsor Site Management Oversight Plan
- Supports operational trial feasibility and approves sites recommended by CRO(s) for trial participation

- Provides training on the protocol and key trial elements together with the MorphoSys Clinical Trial Leader (CTL) and Clinical Program Leader (CPL) to the CRO site management team as needed and drives any other activities that support site selection and recruitment
- Ensures that all essential documents are in place for approval of site initiation and release of Investigational Medicinal Products (IMP) to the sites
- Performs periodic review of protocol deviations, site issues and monitoring visit reports to identify trends, quality / compliance concerns or any other areas for improvement and initiates appropriate actions with CRO site management team and as required with CTL and/or Quality Assurance
- Performs co-monitoring visits with the CRO CRA in compliance with annual co-monitoring plan
- Provides governance on site-specific TMFs maintained by the CRO
- Communicates with CRO site management team on a regular basis to assure proper adherence to protocol, study plans, timelines and other trial related topics
- Participates in MorphoSys CTT meetings as a core member
- Participates in internal audits and HA inspections as required
- Coaches new CTMs during their onboarding as assigned
- Actively contributes or leads process improvement or acts as Subject Matter Experts

Job Qualifications:

- Bachelor’s degree or equivalent qualification in life science / healthcare, Master's degree is preferred
- Ideally more than five years pharmaceutical industry experience with three to five years strong experience in clinical research in a field monitor role or a role overseeing clinical trials
- Thorough knowledge of Good Clinical Practice, regulatory processes, and clinical trial process
- Previous experience in overseeing site management activities on a global level preferred
- Experience with health authority inspections (FDA and/or EMA) preferred
- Strong Project Management and leadership skills
- Strong interpersonal skills
- Highly proficient in negotiation skills
- Working experience in a global team, team player
- Ability to work in a matrix environment
- Ability to work under pressure
- Highly effective in influencing others
- Displays innovative ideas and solutions
- Fluent English (oral and written)

We offer:

- Creative working in X-functional teams
- Open and appreciative corporate culture
- Multicultural environment
- Working in an attractive, high-quality equipped building with restaurant
- Free sports and language courses

Thank you for your interest! We are looking forward to receiving your pertinent application documents. For your application please use exclusively our career portal www.morphosys.com/careers/job-opportunities. We offer not only excellent career prospects, but also support you from the very beginning – even helping you move if necessary.

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