Topas Therapeutics

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Clinical Project Manager/Senior Clinical Project Manager (m/f/d)

Topas Therapeutics GmbH

Hamburg, Germany – Full time

Topas Therapeutics GmbH (Topas) is a clinical-stage biopharmaceutical company focused on developing therapeutics to address areas of major unmet need, e.g., autoimmune diseases, allergies and anti-drug immune responses. Topas' technology platform induces antigen-specific immune tolerance by utilizing the liver's natural immunology capabilities, targeting liver sinusoidal endothelial cells (LSECs), which generate tolerance against bloodborne antigens.

The Company has recruited an experienced leadership team with a successful track record in research, drug development, manufacturing, and operations. Topas' employees are self-motivated, high-performing professionals with diverse backgrounds, who all share the desire to grow, both individually and together, by providing exceptional contributions to the organization. In addition, the company has established a firm network of accomplished advisors with deep experience in pharmaceutical research and development to ensure quick complementary expertise in all relevant areas.

Topas is seeking a ***Clinical Project Manager*** or ***Senior Clinical Project Manager*** with passion and desire to become part of an innovative team committed to developing new therapeutic solutions for challenging diseases. You will be ***an integral member of a cross-functional team*** that consists of highly motivated professionals with deep knowledge and experience in regulatory, drug development, clinical operations, drug safety, and manufacturing. The team is responsible for the successful execution of the Company's strategic objectives and projects in several indications in a cost-effective, safe, and compliant manner.

The successful candidate will ensure the Company's projects and clinical trial(s) are managed to the highest quality in adherence with all applicable regulations.

It is essential that the individual selected for this position is an effective and collaborative team player as well as capable to work independently and to quickly establish rapport and credibility throughout the Company at all levels.

The selected candidate will work directly with Topas' Head of Clinical Operations.

Responsibilities

As an ***integral member of a cross-functional team*** the ***Clinical Project Manager*** or ***Senior Clinical Project Manager*** is leading or managing the planning and conduct of development projects and clinical trial activities. Specifically, he/she

- Develops or provides medical, development and operational input to the development of clinical trial and project documents including clinical development plans, clinical study protocols, investigator's brochures, risk assessments, study-specific plans and manuals;
- Implements, leads, or supports the project team and/or the clinical/study team, or respective sub-teams. Actively drives the proper identification and the setup of such teams to execute, track, and report project and study activities;
- Manages/supports clinical (or preclinical) studies run by CROs during commissioning, at study start, during the study including the day-to-day operational management, and at study closure, including the development of vendor specifications, the review of vendor reports, budgets, metrics, and the timely escalation of risk to timelines and budget if needed in order to ensure that performance expectations are met;
- Oversees monitoring activities at clinical CROs by reviewing visit reports, and any protocol deviations; attend monitoring visits as required;
- Manages/supports the interface management and the preparation/conduct of meetings with external collaborators including co-ordinating investigators, local site investigators and applicable study committees;
- Ensures that operational tracking needs are identified and appropriately managed; regularly communicates the study status and timelines and escalates unresolved issues appropriately;
- Responsible for the implementation of contingencies and measures to overcome operational challenges, in consultation with line management;
- Oversees the timely supply of all materials (from internal and external parties) to sites and CRO/vendors;
- Ensures that assigned studies are conducted according to company SOPs, ICH and regulatory authority standards, specifically including GCP requirements;
- Provides summaries for clinical and/or preclinical study results, based on raw data or summary figures generated by external collaborators and CROs;
- Ensures the timely delivery of project and study documents e.g. Clinical Study Reports and regulatory documents;
- Participates in developing the clinical, scientific, and operational network including consultants, CROs, vendors;
- Responsible for setting up archives for essential documents including Trial Master File, and ensures proper filing of essential documents in these systems.

Additional tasks in case of medical qualification:

- Clinical / medical assessments on project and study level, including indication evaluations, benefit-risk assessments and medical monitoring / medical reviews.

Requirements

- Ph.D. in applicable area, and/or Medical Doctor (M.D.)
- Proven clinical development experience of at least 5 years in management of operational (possibly: and medical) aspects of conducting clinical trials, including trial design, trial organization, development of timelines, budgets and resource plans
- Experience across a range of therapeutic areas

- Experience of leading clinical trial teams, working with vendors (CROs, IVRS, central laboratories)
- Strong understanding of FDA/EMA/ICH guidelines and industry standard practices regarding clinical development and trial management
- Proven ability to successfully achieve results within a multifunctional, multicultural and geographically diverse team
- Excellent written and verbal interpersonal communication, influencing and customer care skills demonstrated by an ability to present clear instruction/direction to team members
- Excellent organization and tracking skills, as well as attention to detail
- Documented training in and experience working with GCP
- Mandatory fluent English (both oral and written) – other languages (German) are an asset.
- Available for approximately 25% travel both domestic and international, including overnight stays

Application:

If you think you have the right skills and experience, and a wish to join a highly motivated team with a passion for science, we invite you to apply at: careers@topas-therapeutics.com. In the e-mail subject line, please indicate the position title: ***Clinical Project Manager*.**

We thank all applicants for their interest, however, only those selected will be invited for an interview.