(Senior) Clinical Trial Manager (m/f/d)
Full-time or part-time

About Tubulis

The development of novel, effective and safe therapies for the treatment of cancer is one of the main challenges for modern medicine. We want to drive this process forward. The main goal of Tubulis is to become a leading company in the field of targeted therapeutics and antibody-drug conjugates (ADCs). With a strong team, our own technologies and innovative therapeutic concepts, we are ushering in a new era in the ongoing fight against cancer and share the vision of helping patients world-wide. Be part of a multidisciplinary and focused team that works towards getting novel promising ADCs to patients with solid and hematological cancers.

Be part of our team

as a proactive and highly motivated Clinical Trial Manager (CTM) / Senior CTM to operationalize our global oncology antibody-drug conjugate (ADC) clinical-stage projects. As CTM / Sr. CTM (m/f/d) you will direct our early-stage clinical trial activities (Ph I/II) and ensure that the studies are completed within budget, in time, and with the highest quality. You will be responsible for managing the planning, implementation, and tracking of the clinical monitoring process, administration of the clinical trials, and maintaining an overview of the studies with the Tubulis Trial Team. You will report to the CMO.

Responsibilities

- Overall responsibility for Tubulis' Phase I/II oncology clinical trial(s). Will expand to subsequent trials as the program and portfolio grow
- Lead the cross-functional Tubulis Trial Team (TTT)and the day-to-day operations of the clinical study to ensure completion per the established goals, objectives and budget in compliance with SOPs/GCP/ICH/regulatory requirements
- Manage the interactions with the Clinical Research Organization (CRO), clinical vendors /partners and coordinate the clinical study timelines with program management to meet critical milestones
- Escalate issues that may jeopardize the deliverables. Proactively identify and resolve issues that arise during study conduct
- Develop study plans and system set-up
- With the team and CRO, perform country and site selection, coordinate site management activities
- Guide, author, audit or edit study documents including data reports, training materials, and operational manuals. Participate in protocol development, Case Report Form (CRF) design, Informed Consent Form (ICF) design, and Clinical Study Report (CSR) writing
- Enable the team to achieve excellent data quality
- Develop and oversee the trial budget

Requirements

- Thorough understanding of the drug development process with strong knowledge of ICH and GCP guidelines
- Extensive knowledge of clinical trial regulations including US FDA and EMA
- 5+ years of work experience in clinical trial management for a biotech or pharmaceutical company, or in a related field
- Bachelor's or master's degree in a science-related field
- Strong experience in the management of CROs and other vendors
- Influential and assertive communication skills (written and verbal)
- Proven project management abilities and study leadership
- Ability to work independently and to prioritize duties
- Proactive team spirit, striving to find best solutions in a collegial team environment
- Fluent English skills, both written and verbal

What we offer

Flat hierarchies and short decision-making processes; open corporate culture; possibility of mobile working; working from Europe or US is possible; unlimited contract after probationary period; 30 days' vacation; strong team spirit; personal appreciation of values; multicultural and global team and high level of collegiality; regular team events; mobility allowance; GUV; pleasant office atmosphere, modern technology standard.

We look forward to receiving your application with details of when you can start and your salary expectations.

By email to career@tubulis.com – more information at www.tubulis.com