Senior Clinical Trial Associate (m/f/d) Full-Time

Company: We are Immutep, an emerging international biotechnology company developing immunotherapeutic products for cancer and autoimmune diseases. With operations based in Australia, Germany and France, Immutep is dedicated to bringing innovative treatment options to patients. The company is publicly traded on the ASX and NASDAQ.

Location: The Clinical trial Associate will be office-based in Berlin, Germany or willing to travel regularly to Berlin.

Summary: As a result of continuous progress in our projects we want to expand our team and therefore seek a highly motivated and experienced Senior Clinical Trial Associate to join our dynamic team. You will play a crucial role in supporting the Clinical Trial Manager (CTM) and any other team member, as necessary, in the day-to-day clinical operations activities for the planning, execution, and management of assigned clinical trial(s). Strong candidates will bring knowledge and experience in the fundamental aspects of trial and study site management, vendor management, and experience in the full cycle of study from start-up to close out. This position will report to the Head of Clinical Operations.

Main responsibilities:

Clinical Operations Support:

- Provide administrative support for designated clinical research personnel including CTMs in accordance with applicable local laws, international guidelines, and SOPs.
- Provide overall support to the clinical team from study startup to closure: e.g., prepare meeting agenda, summarize meeting minutes, support in preparing presentations, regular status reports etc.
- Collaborate with the CTM to ensure the smooth execution of clinical trials.
- Assists the CPM with Sponsor oversight, study specific documentation review and QC including review of informed consent form, study plans, study reference manuals, eCRF, etc.

- Assist with creation and maintenance of study metrics trackers, tools and reports.
- Assist the clinical team in interacting with CROs, vendors and collaborators.
- Contribute to streamlining processes in assigned studies.
- Assist in coordination and tracking of Investigator and third-party payments.
- Support the review and tracking of invoices from vendors/consultants.

Documentation and Record Keeping:

- Maintain and organize trial documentation, ensuring compliance with regulatory standards, company SOPs and ensuring all documentation is in a state of audit readiness.
- Responsible for up to date filing in the in-house part of the trial master file (TMF). Perform TMF QC activities per SOP and oversee coordination of issue remediation where needed.
- Assist the CPM with Sponsor oversight of CRO-held eTMFs periodic audit and findings resolution.
- Preparation and review of essential trial documents, as necessary.
- Contribute to the review and QC of clinical core documents (e.g., Investigator Brochure, trial protocol, trial amendments, patient information sheet and consent form).
- Support the preparation, conduct and follow-up of GCP audits and GCP inspections.
- Assist with archiving study documents for completed clinical trials

Site Management:

- Liaise with investigational sites, as necessary, to facilitate the timely initiation and conduct of trials.
- May contact clinical sites/CRO for specific requests (e.g., enrolment updates, missing documentation, meeting arrangements, etc.. when requested).
- Assist in the tracking and resolution of site-related issues.
- Assist the CPM and clinical team with Investigator Meeting coordination, activities preparation and generate meeting minutes.
- Assist in quality assessment visits, if applicable.

Protocol Compliance:

- Assist in ensuring adherence to study protocols, regulatory requirements, and SOPs.
- Assist in the development and implementation of training materials for site/CRO personnel.

Cross-Functional Collaboration:

- Work closely with cross-functional teams, including regulatory, data management and quality assurance, to achieve project milestones.
- Participate in internal and external meetings as a representative of the clinical operations team and generate meeting agenda and minutes as needed.

- Other duties may be assigned as required.

Skills/Experiences/Qualifications:

Essential

- **3-5 years' experience as a CTA or experience in a similar role (e.g., Project Specialist, Clinical Study Coordinator) preferably on the Sponsor/pharma side**
- Knowledge and experience in relevant legislation and international guidelines (ICH-GCP) for the performance of clinical trials.
- Experience and knowledge of eTMF management, CTMS preferable.
- Proficient in standard software (Word, Excel, Outlook, Power Point); CTMS/EDC systems.
- Display excellent organisation and time management skills, excellent attention to detail, and ability to multi-task in a high-volume environment with shifting priorities.
- Good interpersonal skills and ability to work in a team environment with a collaborative approach.
- Proficient in English (written and spoken). Strong verbal and written communication skills.
- Residency in Berlin or other German city with the ability to relocate on short notice, or travel to Berlin regularly.

Preferable

- Scientific or healthcare field educational background, preferred.
- Experience in oncology, immune oncology is a plus.
- Experience in large phase II or phase III studies is an asset.

What we offer:

- Multifunctional interesting tasks in the emerging field of immune therapeutics.

- Be part of the development of a “first in class” immune oncology drug
- Highly motivated, energetic and supportive international team.
- Competitive compensation.

We kindly ask to send applications in English.

If you are interested in this challenging career opportunity, please send your CV, salary expectations, application letter and your earliest possible entry date to the following e-mail address (confidentiality is of course guaranteed):

hr-germany@immutep.com

In case of questions you are welcome to contact us via email.

privacy statement for applicants