Immutep is hiring:

Senior Clinical Trial Associate (m/f/d): Permanent Contract

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:

Berlin, Germany; full-time, hybrid role (office/remote)

Summary:

As a result of our continuous progress in our projects, we are looking to expand our team and are therefore seeking 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 other team member, as needed, in the day-to-day clinical operations activities involved in the planning, execution, and management of assigned clinical trial(s). Ideal candidates will have a solid background in trial and study site management, vendor management, and hands-on experience with the full study lifecycle, from start-up to close out.

Job Description:

Clinical Operations Support: Collaborate with the CTM in admin & management tasks (e.g.):

- Investigator Meetings: support CTM with agenda, minutes, communication, coordination.
- Assist the CTM with Sponsor oversight.
- Ad-hoc tasks as requested by the CTM.
- Training entry level CTAs.
- Support the preparation, conduct, and follow up of audits/inspections.
- Participate in Protocol Deviation (PD) reviews and coordinate as necessary in place of the CTM.

Documentation and Record Keeping: Collaborate with the CTM in admin & management tasks (e.g.):

- Support identification and analysis of potential risks with CTM. Support Follow Up (FU)/coordination as needed.
- Possess comprehensive knowledge of the Trial Master File (TMF); ensure the completion and quality control (QC) of the eTMF, including at the Contract Research Organization (CRO) level, and promptly resolve any issues
- Review Change Orders (COs)/Work Orders (WOs) incl. budgets, and invoices along with the CTM.
- Manage insurance certificate updates.

- Develop & Review/QC core clinical docs (e.g., trial protocol, CSR, PoP, PoR, study-related plans & form/logs.
- Develop tracking tools and processes along with the management of information in those tools.

Site Management: Collaborate with the CTM in admin & management tasks (e.g.):

- Review Monitoring Visit Reports (MVRs) for any discrepancies. Communicate feedback to CRO.
- Coordinate the site selection process internally by circulating trackers, scheduling meetings, and FU with the CRO to address any questions.
- Participate in Quality Assessment Visits (QAVs) and perform tasks independently. Support FU, conduct, oversight & plan as delegated by the CTM.

Cross-Functional Collaboration: Collaborate with the CTM in admin & management tasks (e.g.):

- Lead team meetings, prepare meeting agenda, summarize meeting min, & ensure FU/completion of meeting action items.
- Support with CRO/Vendor Selection meetings, slides, agendas, coordination etc.
- Liaise with CROs and other vendors to ensure deliverables and methods of communication are developed to facilitate efficient workflow.
- Can manage and be the main contact person for a particular vendor as delegated by the CTM.

Skills/Experiences/Qualifications:

Essential

- **3-5 years' experience as a CTA or experience in a similar role (**e.g., clinical site, CRO, Sponsor or clinical trial vendor) preferably on the Sponsor/pharma side.
- Knowledge and experience in relevant legislation and international guidelines (ICH-GCP) for the performance of clinical trials.
- Advanced understanding & demonstration of proficiency in CTA tasks. Experience setting up & maintaining eTMF.
- Very good knowledge of standard software (Word, Excel, Outlook, Power Point); knowledge of CTMS/EDC Systems.
- Very strong skills in collaboration, communication, organization, prioritization of tasks & attention to detail.
- Strong professional and interpersonal communication skills, with the ability to engage effectively with others.
- Perform multiple tasks simultaneously and manage changing priorities; must be comfortable working in a fast-paced environment.
- Sound analytical and problem-solving skills; able to work under minimal supervision for the tasks assigned.
- Critical thinking: able to assess complex information with support from CTM.
- Proficient in English (written and spoken). Strong verbal and written communication skills.

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.

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

Privacy Statement for Applicants