Immutep is hiring:

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

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

Location: Berlin, Germany; full-time

Summary: As a result of continuous progress in our projects we are hiring a (Senior) Clinical Trial Manager. You will be responsible for one of our international clinical trials. This implies the preparation and processing of national and international projects under consideration of local laws, international guidelines (ICH GCP) and applicable SOPs. You will be responsible for the timely performance of all services, control of third-party providers, as well as problem management by interacting with all internal departments and external vendors involved.

Job description:

- Trial management of national and international clinical studies in accordance with GCP, applicable local laws, international guidelines and SOPs
- Provide regular status updates to the director of clinical development (and the senior management)
- Oversee clinical trials in regards but not limited to status, budget, safety and quality
- Prepare and contribute to clinical core documents (e.g. Investigator Brochure, Trial protocol, trial amendments, Patient information sheet and consent form, Case report forms and others)
- Set up and maintain the clinical trial database/tracker
- Ensure the setup and maintenance of the TMF/ISF (TMF is handled by CRO)
- Ensure timely submission of all required trial applications to Competent Authorities and Ethic Committees/Independent Review Boards
- Organize and conduct investigator meetings
- Support the process of country and ensures site selection
- Vendor and CRO management; serve as main contact for outsourced activities, and manage CRO, if applicable
- Conduct Co-Monitoring visits, as applicable
- Support preparation, conduct and follow-up of GCP audits and GCP inspections
- Support the director clinical development on program level documents

Skills/Experiences/Qualifications:

- Natural/ life sciences or medical background (university degree or experience in a medical profession such as Nurse or Medical Technical Assistant or Pharmaceutical Technical Assistant)
- Profound knowledge and experience in relevant legislation and international guidelines (ICH-GCP) for the performance of clinical research projects
- Minimum 3 years (5 years is a minimum for the senior position) of experience in clinical trial management with practice in project planning and structuring on CRO or sponsor side
- Experience with regulatory submissions, monitoring of clinical trials, (immune) oncology is a plus
- Refined colloquial and correspondence skills in English (written and spoken)
- Very good German (written and spoken) is a plus
- Very good knowledge of standard software (Word, Excel, Outlook, Power Point, CTMS/EDC systems)
- Sound understanding of clinical evaluations and regulatory affairs processes
- General understanding of R&D processes especially in Biotech companies

Job expectations:

- Multifunctional interesting tasks in the emerging field of immune therapeutics
- Be part of the development of a "first in class" drug
- Highly motivated and energetic international team
- Permanent contract, office based
- Competitive compensation

If you are interested in this challenging career opportunity, please send your CV, certificate of employments, salary expectations, application letter and your earliest possible entry date until January 31st, 2019 to the following e-mail address (confidentiality is of course guaranteed):

hr-germany@immutep.com

In case of questions you are welcome to contact the Berlin office via +49 30 88716843.

privacy statement for applicants