Clinical Study Manager

BioPorto Diagnostics is in search of a Clinical Study Manager who will be a key member of the Clinical Operations team with a high knowledge of clinical and study operations and the ability to lead all operational aspects of assigned clinical studies. This role will support and lead, as assigned, successful pre-clinical and clinical trial planning, implementation, execution and delivery within specified quality, time, and cost parameters.

About us

BioPorto is an in vitro diagnostics company that provides tests and antibodies to clinicians and researchers around the world. We use our antibody and assay expertise to transform novel research tools into clinically actionable biomarkers that can make a difference in patients' lives. BioPorto is headquartered in Hellerup, Denmark, and is listed on the NASDAQ Copenhagen stock exchange. In November 2023, we received FDA Clearance for ProNephro AKI (NGAL), the first cleared biomarker for pediatric AKI risk assessment.

Our people

BioPorto has approximately 35 dedicated employees globally. We have a roll-up-your-sleeves attitude, where we help each other achieve our common goals in biomarker development and promotion. Our organization is energetic, passionate, and committed to providing a supportive work environment.

Your role

Please note that this position is US-based. Your primary responsibilities will be to:

- Manage and oversee all operational components of assigned clinical trials, including start-up, conduct, and close-out of studies.
- Ensure that clinical trial and study activities and deliverables are completed on time in accordance with appropriate quality standards including GCP/ICH requirements and BioPorto SOPs.
- Participate in identifying, evaluating, and selecting clinical sites in collaboration with the Clinical Research Organization as applicable.
- Be responsible for site management oversight and clinical monitoring ensuring high quality and timely data collection.
- Participate in ongoing study data reviews and data cleaning activities.
- Develop and provide ongoing maintenance of clinical study tools and templates such as Clinical Monitoring Plans.
- Assume responsibility for TMF setup and maintenance.
- Assist in vendor selection and oversight (CRO and Data Management).
- Coordinate and track initial and ongoing protocol-specific training of the study team.
- Provide study status updates and reports to senior management.
- Contribute to the development and review of Clinical Operations work instructions and SOPs.
- Provide support to R&D or other departments in the execution of non-clinical trial study activities.

Your qualifications

- Bachelor's degree or higher in scientific or healthcare discipline preferred.
- 3-5 years of experience in clinical research or clinical operations within the Biotech or IVD industry.
- Experience in clinical and research laboratory operations highly preferred.
- Experience with Electronic Clinical Trial Management Systems (CTMS), Electronic Data Capture (EDC) and Trial Master Files (TMFs).
- Knowledgeable in GCP and other applicable regulations and standards.

As an individual, you are flexible and able to meet timelines while managing multiple activities. You can work independently, ensuring high-quality standards and attention to detail. You enjoy a dynamic working environment where effective teamwork is critical to succeed.

Our offer

We offer you an exciting and dynamic position, with great personal and professional development opportunities. You will work in a small and informal team, collaborating with other departments where your expertise and opinion will be valued.

Additional Information

Please send your application and CV **in English** using the link: http://www.bioporto.us/careers

Your application will be treated with confidentiality.

Interviews will be performed in parallel to the application period. We reserve the right to proceed with the employment process if the right candidate is identified during this period.

BioPorto provides equal employment opportunities to all employees and applicants for employment and prohibits discrimination and harassment of any type without regard to race, color, religion, age, sex, national origin, disability status, genetics, protected veteran status, sexual orientation, gender identity or expression, or any other characteristic protected by federal, state or local laws.

This policy applies to all terms and conditions of employment, including recruiting, hiring, placement, promotion, termination, layoff, recall, transfer, leaves of absence, compensation and training.