Clinical Trial Lead (CTL)
Location: Remote, Europe

COMPANY OVERVIEW

BVI® is refocusing the future of vision. As one of the fastest-growing, diversified surgical ophthalmic businesses in the world, our purpose-built portfolio spans more than 115 countries. We've set our sights on touching the lives of millions of patients affected by conditions such as cataracts, refractive error, glaucoma, retinal disease, and dry eye.

Unburdened by legacy or bureaucracy, we have developed our strategy around a simple concept — taking pride in delivering innovative solutions for our physicians and patients, based on their needs. We trust and empower our associates to make decisions and solve problems because collaboration drives us. Valuing agility, simplicity, and transparency, we stay committed to listening to our customers, delivering for our patients, and keeping the future in focus.

PURPOSE

Accountable for all aspects of assigned clinical trials (pre-and post-market). Lead the Clinical Trial Team (internal or external), who is responsible for planning, executing, and reporting of clinical trials. Author robust clinical documentation with scientific integrity and quality.

RESPONSIBILITIES

- Lead the global clinical trial team who is responsible for planning, conducting, and reporting on all clinical trials within Global Clinical and Regulatory Affairs, including trials for Registration and Post-Marketing.
- Contribute medical/scientific/feasibility input for the development of the protocol synopsis. Collaborate with the Medical Advisors to ensure expert feedback is adequately integrated into the protocol.
- Ensure protocol and all auxiliary documents, including manual of procedures, informed consent template, investigator brochure, statistical analysis plan, data validation plan, etc. are written in high quality and available.
- Ensure trials are carried out according to the protocol, SOPs, and ISO/GCP regulations.
- Forecast trial resource needs. Accountable for the development, management and tracking of trial budget. Obtains approval for trial budget. Independently ensure quality and timely execution of a clinical trial within timeline and budget.
- Manage feasibility assessment to select relevant regions and countries for the trial.
- Identify, select, and monitor performance of investigational sites for clinical trials.
- Define scope of work and contract requirements for clinical trial vendors. Oversees vendor conduct of tasks.
- Interface with different departments to ensure that clinical activities are in line with overall strategic goals including: Quality, R&D, Marketing and Sales.
- Oversee and provide input to clinical supplies forecasting, device accountability and device reconciliation.
- Supervise set-up and maintenance of enterprise content management systems such as Clinical Trial Management System (CTMS), Trial Master File (TMF) etc.
- Other duties as required

REQUIRED KNOWLEDGE, SKILLS AND ABILITIES

Knowledge

- University degree in Medical Science or equivalent education required. Advanced degrees (e.g., MS, MD, PhD, O.D., PharmD) are preferred.
- 6+ years in clinical research or relevant scientific, industry, therapeutic or geographic experience
- Relevant industry experience includes experience in planning and execution of clinical studies in various phases and geographies
- Solid understanding of the integrated development process of medical devices and/or pharmaceuticals
- Solid understanding of the clinical trial regulations and guidelines (GCP, FDA, MDD, MDR, EMA, ICH, ISO, ANSI, etc.)
- Strong background in ophthalmology
- Fluent in English

Skills

- Strong interpersonal, verbal and written communication skills.
- Effective presentation skills
- Organizational awareness to operate in a cross-functional team
- Well organized / strong project management skills

Abilities

- Ability to proactively identify issues, respond appropriately and provide guidance for pro-active resolution
- Experience in running clinical studies independently without significant supervision
- Ability to embrace and communicate change
- Ability to establish clear directions and set stretch objectives
- Ability to balance strategic and tactical objectives
- Demonstrated ability in managing technology systems to accomplish work objectives

Behaviors

- Aligns and energizes team members behind common objectives
- Possesses scientific thinking allowing to identify bias and validity issues
- Establishes and maintains effective working relationships with coworkers, managers and clients

MINIMUM REQUIRED EDUCATION AND EXPERIENCE

- Bachelor's degree in Healthcare or related field and 3 years relevant experience; or equivalent combination of education, training, and experience

PHYSICAL REQUIREMENTS

- Extensive use of keyboard requiring repetitive motion of fingers.
- Extensive use of telephone and face-to-face communication requiring accurate perception of speech.
- Regular sitting for extended periods of time.
- May require occasional travel.

Interested? Submit a **cover letter** and **C.V.**
to TalentAcquisition@bvimedical.com

Beaver Visitec International is an Equal Opportunity/Affirmative Action employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability, or protected Veteran status.

The above information on this description has been designed to indicate the general nature and level of work performed by employees within this classification. It is not designed to contain or be interpreted as a comprehensive inventory of all duties, responsibilities and qualifications required of employees assigned to this job.

Important notice to Employment businesses/ Agencies
BVI does not accept referrals from employment businesses and/or employment agencies in respect of the vacancies posted on this site. All employment businesses/agencies are required to contact BVI's human resources department to obtain prior written authorization before referring any candidates to BVI. The obtaining of prior written authorization is a condition precedent to any agreement (verbal or written) between the employment business/ agency and BVI. In the absence of such written authorization being obtained any actions undertaken by the employment business/agency shall be deemed to have been performed without the consent or contractual agreement of BVI. BVI shall therefore not be liable for any fees arising from such actions or any fees arising from any referrals by employment businesses/agencies in respect of the vacancies posted on this site.