# Regional CRA Manager
# 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

In collaboration with project team leaders, the Regional CRA Manager is responsible for supporting the planning, monitoring, and coordination of study activities at external study sites. As part of these activities, the Regional CRA Manager will oversee all assigned CRAs, and ensures all monitoring deliverables are provided in a high-quality manner in support of project objectives. This position may be a remote location in Europe.

## RESPONSIBILITIES

- Performs gap assessments in sponsor monitoring capabilities, and coordinates appropriate CRA resourcing needs across all clinical trials
- Coordinates all monitoring aspects in the execution and support of clinical trial activities
- Supervises and ensures CRA team members are compliant with SOPs, sponsor, and regulatory agency expectations for site monitoring activities
- Participates on internal, site and sponsor teleconferences and meetings to address monitoring activities outlined in statements of work
- Reviews study protocols, relevant study documents, monitoring reports, and project plans for communication, monitoring, and other study plans
- Develops and implements full scope and risk-based monitoring programs
- Develops and implements key monitoring metrics and associated tracking systems, and evaluates defined milestones for these activities in relation to available resources
- Reviews and approves travel expenses, expense reports and timesheets
- Conducts co-monitoring visits (Capabilities Assessments, Evaluation Visits, Activation Visits, Interim Visits, Close-out Visits, Audit Preparation Visits, and other visits) as required
- Participates as a CRA team leader in project planning, implementation, problem solving, tracking milestones and deliverables
- Liaises with vendors as appropriate
- Leads in the development of key monitoring deliverables such as study/site monitoring plans, general monitoring guidelines, monitoring SOPs, and site visit report templates
- Identifies, trains, and mentors new CRAs and monitoring staff
- Preparation of monitoring budgets and statements of work for existing and new proposals, as needed

## REQUIRED KNOWLEDGE, SKILLS AND ABILITIES

### Knowledge

- Bachelor's degree and a background in clinical research, public health, biological sciences, or other related fields
- 5 years of monitoring experience in medical device clinical trials preferred
- Prior experience in any of the areas of ophthalmology, optometry, and surgical instrumentation preferred
- ACRP CCRA or equivalent certification preferred

### Skills

- Proven supervisory 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 independently plan and facilitate teleconferences and meetings with clinical staff, vendors, and sponsor representatives
- Ability to proactively identify issues, respond appropriately and provide guidance for pro-active resolution
- Experience in supporting clinical trials 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
- 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

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*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.*

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