CLINICAL STUDY MANAGER

HOME BASED IN SWITZERLAND OR EUROPE

THE COMPANY

Are you passionate about innovation and groundbreaking development? Do you want to join an organisation where you can really make an impact? Have you got experience in designing and managing clinical studies?
If yes, we have a fantastic opportunity for you!

This is a chance to join an extremely well funded, early commercialisation stage company with over 1000 patents - a huge innovation portfolio. Right now they are developing and bringing to market not one, but FOUR Class III active and (non active) implantable medical devices that are about to totally change the status quo.

With the continuous growth and development, the company is looking for a strong Clinical Study Manager to be responsible for Pre-CE, CE mark and PMCF studies globally.

THE OPPORTUNITY

You will have the opportunity to step into a brand new position as Clinical Study Manager, no old shoes to fill here, and really shape not just your position but also the direction of the clinical department. This company has built, and is continuing to build, clinical as a key partner in the business so you can be sure to make an impact on the future of the organisation. From designing to implementing to managing; you will lead all phases for the clinical study.

YOUR RESPONSIBILITIES:

- Design and manage clinical studies in Europe and US
- Develop and review documents, presentations and processes specific to the study and create study reports for the clinical parts of regulatory submissions
- Coordinate cross functional teams throughout clinical studies including quality and regulatory affairs in order to ensure alignment and compliance to the company's goals and necessary regulations
- Develop and execute Clinical strategy for the company for various projects as they arise
- Write clinical study protocols for Pre-CE, CE mark and PMCF studies
- Write PIS/ICF documents
- Assure compliance with SOPs and local regulations as well as CFR and GCP guidelines
- Build and maintain key relationships with competent authorities on a local and international level
- Create and oversee the trial budget
- Create and implement study-specific clinical monitoring tools and documents
- Coordinate and supervise clinical monitoring team
- Conduct site initiation visits
- Travel up to 30% in EU and internationally when arranging and overseeing site visits

YOUR QUALIFICATIONS:

- 5+ years experience working on clinical studies for Europe AND/OR the US
- Experience with active OR implantable medical devices
- Fluent speaking, reading and writing in English

INTERESTED TO EXPLORE THIS FURTHER?

Please send your CV to kristina@elemed.eu to arrange a confidential career discussion.