Senior Clinical Research Associate / Senior Field Clinical Specialist (with focus Proctoring duties)

Job Title: (TBD)

Location: EU (home based – travel requirement up to 60%)

Starting date: 01 Mar 2025 or TBD

Company: CorFlow Therapeutics AG

Web: https://corflow.com/

About Us: CorFlow is a Swiss med-tech start-up founded in 2016 by renowned interventional cardiologists and medical device entrepreneurs. The company recently completed a major financing round which enables the expansion of the clinical program and employee team.

At CorFlow, we envision being the leader in diagnostic and therapeutic solutions for restoring healthy microvascular blood flow anywhere in the human body where a critical need exists. We are developing a medical device that assess Microvascular Obstructions (MVO) in real-time during PCI and serves as a treatment platform while the patient is still in the cath lab.

Our mission is rooted in scientific excellence and driven by compassion for the welfare of Acute Coronary Syndrome (ACS) patients.

CorFlow's 1st generation device has been investigated in a First-in-Human multi-center European clinical trial, and CorFlow recently finished the development of the 2nd generation device which can be used in the next clinical studies.

We seek a Senior Clinical Research Associate (SCRA) or Senior Field Clinical Trial Specialist (SFCTS) to support our Europe-based clinical activities, including proctoring, technical case support, and study management tasks for current and future trials. CorFlow is initiating an FDA pivotal trial with international sites and a second randomized study conducted exclusively in Europe.

Job Description:

The position includes a diverse set of duties. In addition to your critical role in overseeing and managing clinical trials, you will take on advanced proctoring responsibilities.

As a Proctor, you will train study site staff on the correct use of the study device and provide input during live cath lab procedures. Periodic technical case support at investigator sites is also expected to ensure safe and effective use of the CorFlow technology, meeting study protocols.

If you are a proactive, collaborative, service-minded, and detail-oriented individual with a passion for advancing medical research and a proven track record in medical device clinical trials, **we encourage you to apply**.

Key Responsibilities

Proctoring and Case Support Duties

- Train assigned study staff on the correct use of the study device.
- Supervise/support the setup of the required site workflow to ensure ideal basis for enrolment and that study images and measurements are collected and of consistent quality.

- Maintain detailed proctoring records and documentation.
- Assist remotely or on site during live cases by supporting site staff in the correct use of the CorFlow study device and the CIP.
- In agreement with CPM, release clinical sites to independent use of the study device.

Clinical Trial Support

- Manage clinical trial activities in alignment with the clinical project manager (CPM), from study initiation, enrolment to study close-out.
- Train and educate site staff on study CIP, the correct use of the study EDC software, the electronic Investigator Site File (eISF), and regulatory requirements.
- Conduct site qualification, initiation, monitoring, and close-out visits to ensure CIP adherence and data integrity.
- Collaborate with investigators and study site staff to resolve issues and ensure timely and accurate data collection.
- Work in close collaboration with the study-assigned CRO (if applicable)

Regulatory Requirements Support

- Assist in preparing EC/IRB submissions and documents, as needed.
- Assist in internal and external audits and inspections at study sites, ensuring compliance with regulatory requirements.

Data Management

- Ensure accurate and timely data collection in eCRF, monitoring, and validation according to the CIP and associated documents.
- Collaborate with data management team and clinical sites to resolve subject data discrepancies.

Desired Qualifications

- Bachelor's degree in a relevant life science or healthcare field, master’s degree preferred.
- Relevant experience as Clinical Research Associate, Clinical Field Trial Specialist, Field Technical Specialist or similar in the medical device or CRO industry.
- Proven experience in proctoring and site management preferred.
- Fluent French and/or, Spanish and/or Italian (both written and spoken) .
- Fluent English (both written and spoken)
- Good knowledge of GCP, ISO 14155, and relevant EU regulatory requirements.
- Strong organizational skills and attention to detail.
- Good communication and interpersonal skills.
- Ability to work independently and collaboratively in a fast-paced environment.
- Proficiency in using CTMS and EDC software solutions.

- Proficiency in additional languages (Italian, German, and/or Spanish) are preferred.
- Willingness to travel up to 60-80 % within EU.

Benefits: We offer a full-time contract with a competitive package and career opportunities in a pioneering start-up environment.

How to Apply:

If you possess the required experience and qualifications and want the challenge of growing with our company, please submit your application including your latest resume, cover letter and/or a short personal video* (max 2 min) with your motivation.

Sara Specchia | HR Manager | sspecchia@corflow.ch | +41 76 216 27 53

**video download link preferred*

Corflow Therapeutics AG is an equal employment opportunity employer. We celebrate diversity and are committed to creating an inclusive environment for all employees. Employment and advancement opportunities are available to all individuals regardless of their race, color, national origin, religion, ancestry, citizenship status, sex, sexual orientation, gender identity or expression, age, marital status, family responsibilities, pregnancy, disability, or any other protected characteristic.

Note: This job description is intended to provide a general overview of the responsibilities and qualifications for this position. It is not an exhaustive list, and duties may evolve over time based on the needs of the organization.