



SMERUD
MEDICAL RESEARCH

Clinical Research Associate(s) for Denmark Hørsholm-based

The position

SMERUD is looking for a highly motivated and self-going Clinical Research Associate, ideally with hands-on experience from monitoring clinical trials either in the industry or in academia. Candidates will join our Scandinavian clinical operations department with headquarter in Oslo, and with colleagues also based in Uppsala.

Currently we have no employees in Denmark, but we are contracting with two freelancers. As we have secured several new contracts, we aim to re-build our Danish group within short, and aim to hire 2 CRAs now, as well as a Regulatory Affairs Manager and a Market Access Manager. All staff report to our headquarters in Oslo, Norway.

Responsibilities

Most of our clinical trials are early stage, typically phase 1 and 2; and the majority of our clients are smaller biotech companies. Thus, you will be expected to have sufficient experience to work independently, and in a small organisation. Our CRAs will coordinate clinical trials between sponsor, clinical sites and public authorities. Primarily, you will monitor clinical sites across all of Denmark, but may also be allocated to cover sites in Sweden and Norway for certain projects. Duties include:

- In-house management of investigational sites in clinical trials
- To conduct periodic monitoring visits at investigational sites participating in clinical trials. This also includes:
 - pre-study visits
 - initiation visits
 - periodic monitoring visits
 - close-out visits
- Have responsibility of study medication and equipment accounting; i.e. planning, ordering, receipt, distribution and collection to and from the storage facilities in the company and investigational sites. To keep an updated register of drug and equipment accountability for each participating investigational site.
- To assist the project manager in the planning and closing phase of the project; e.g. protocol writing, development of patient information and informed consent form, development of case report forms, and application to applicable authority bodies and ethics committees.
- To participate in secondary (in-house) monitoring of other projects for which the CRA does not have primary monitoring responsibilities.
- To assist data entry manager in preparing data for entry into database programmes.
- To work according to the latest standard operational procedures and in strict conformance with the company's good business practices and ethics

Qualification

- Practical experience in clinical trial monitoring
- Relevant life science education, ideally Master degree
- Strong fluency in English and a Scandinavian language, oral and written.
- Excellent presentation and communication skills
- Integrity and professional attitude
- Energetic and flexible with high working capacity and result oriented approach
- Accurate, highly structured and analytical

Location

- Hørsholm (Denmark)

Our offer

- Exceptional learning potential and professional development, as clients are mainly small biotech start-ups and projects cover a wide variety of therapeutic areas
- Environment of leading strategic, operational and scientific expertise
- International projects, local support
- Interactive and flexible corporate working life, with short lines of command
- Competitive and attractive salary

The company

The Smerud Medical Research Group (SMERUD) has been operating for 28+ years as a full-service clinical Contract Research Organisation (CRO). We operate in Northern Europe with head office in Norway and subsidiary offices in Denmark, Finland, Sweden, United Kingdom, Germany, Austria and Poland. Our core services are related to clinical trial activities, primarily clinical project management, monitoring, pharmacovigilance, regulatory affairs, data management, biostatistics, medical writing in addition to our general drug and device development consulting. We have about 30 clinical development professionals employed, with an additional 20 freelancers and consultants associated.

Contact

For further information about the position and the company, please contact our COO Charlotte Kleiveland, at charlotte.kleiveland@smerud.com or visit: www.smerud.com.

Application

Please submit your written application with a full CV in English to human.resources@smerud.com or to Smerud Medical Research International AS, Thunes vei 2, N-0274 Oslo, Norway; marked 'CRA Denmark'. **Deadline: 10 November 2021.**