At Sillar Clinical we are currently looking for experienced CRA / TM (Clinical Research Associate / Trial Monitor). A CRA / TM is responsible for overseeing the progress of a study and ensures that the study is conducted, recorded and reported in accordance with the GCP/ICH guideline, applicable regulatory requirements and relevant SOPs.

For initial consideration, a candidate must meet the following criteria:

- Have experience working as a CRA / TM for several years.
- Fully proficient in reading, writing and speaking Dutch, French and English.
- Must be a resident of Belgium
- A bachelor or master degree in a medical, health or science related area
- Excellent knowledge of Good Clinical Practice (GCP-ICH)
- Knowledge of local regulatory, ethics and institutional contract procedures and submissions

Considered as an asset:

- Experience in vaccines
- Experience in medical devices

Skills

- Must be willing to travel if required.
- Good problem solving and analytical skills
- Service orientated approach, flexible and open to change
- Ability to work unsupervised taking responsibilities for own actions
- Excellent interpersonal and organisational skills
- Be IT-minded and proficient in using cloud solutions and MS Office applications.

Major Responsibilities

- Preparation and/or review of any kind of study documents, Monitoring Guidelines, CRF Completion Guidelines, Patient Information and Informed Consent Form etc
- Prepare the submission to the Independent Ethics Committees (central and local) and when applicable to Competent/Regulatory Authorities
- Participates to Investigators selection/feasibility: e.g. phone contacts, questionnaire in the appropriate country
- Conduct of site qualification visits (pre-study visits)
- Conduct of site initiation- and site close out visits
- Conduct of regular on-site and remote monitoring visits
- Writes visit reports and corresponding site visit follow-up letter for the purpose of on-site quality optimization
- Responsible for the quality of data from his/her own sites
- Resolves questions/issues with investigator/trial staff including query verification
- Resolves and writes queries, and reviews data-listings
- Manages his/her own visit schedule, appointments and the follow-up of issues, along with regular communication with the sites and the clinical study team
- Maintain close contact with the investigators on-site, the study coordinator, the pharmacist and other involved parties to be aware of any possible patient enrolments, the enrolled patients' status, the IP stock and any further site requests or problems
- Filing and update of study documentation in the Investigator Site File and Pharmacy File (if applicable) and the TMF
- Review of Trial Master File (TMF) and ensure that all documents are in order, logical, accurate, complete, up-to-date and ready for a study audit and/or inspection
- Participates in investigators meetings and assists in the preparation of these meetings

Offering:

- Ability to work home-based on regular basis
- Competitive salary (company car, health insurance, meal vouchers, …)
- Working in a small company in full expansion means that your contribution to the growth of company will be appreciated

To apply contact Stijn Otte at finance-hr@sillar-clinical.com with CV and motivation letter.