



It's all about trust

## TFS

TFS, with headquarters in Lund, Sweden, is the largest non-listed European clinical Contract Research Organization (CRO). Clinical services are provided by four business areas; TFS Explore™, TFS Develop™, TFS People™ and TFS Academy™, with annual net revenue greater than € 40 million, global operations in 21 countries, and 500 employees worldwide. Detailed information about TFS business areas, global locations and recent press releases can be obtained at [www.tfscro.com](http://www.tfscro.com)

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## Senior Clinical Research Associate (sCRA) / Project Leader

TFS is a CRO with highly committed and competent employees, who either work as outsourced consultants at pharmaceutical or biotech companies, or work with project assignments in-house.

A sCRA / Project Leader is a member of the Study Team, and is responsible for the initiation, monitoring and termination of tasks during the study process according to company policies, SOPs and regulatory requirements.

The position is full-time and you will either be located at one of our Swedish offices in Stockholm, Lund or Gothenburg or at one of our client's facilities.

### The main responsibilities of the sCRA/Project Leader will include:

- Communication between TFS/Sponsor and the study sites for activities related to site management.
- Site management of the study, i.e. site visits, monitoring, document filing and archiving after closure, telephone contacts, and correspondence, study budget management and invoicing. The monitoring process should be performed in accordance with ICH-GCP, the SOPs of either TFS or the Sponsor and relevant legislation.
- Coordinating the completion of study documentation such as: study protocol, CRFs, patient diaries, Monitoring Manual, Study Operations Manual, Source Data Verification Plan, study report, etc.
- Supporting the submission of local documents to Ethics Committees and the Competent Authorities, and preparing biobank agreements and Data Inspection applications.
- Negotiating local/central laboratory/pharmacy agreements.
- Overall responsibility for planning and presentation at Investigator's meeting(s).
- In cooperation with/under supervision of the Safety Manager coding adverse events, concomitant medication and concurrent diseases.
- Preparing study documentation and assisting the Clinical Quality Assurance Manager/regulatory authorities during audits/inspections in-house or on site.





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**Requirements/Qualifications:**

- Educated to degree level (biological science, pharmacy or other health-related discipline preferred), equivalent nursing qualification or other equivalent experience
- Education in Clinical Research or LIF Diploma course in GCP Monitoring highly desirable.
- At least 3 years experience as CRA including all steps of the clinical study; i.e. site initiation, site monitoring and site closure
- Excellent communication skills in English.
- Good organizational skills and social skills.
- Ability to maintain effective, professional communication.
- Ability to prioritize and manage multiple tasks.
- Ability to manage and supervise study team members as lead CRA.
- Good pedagogical skills.
- Experience of clinical studies in Norway or Denmark highly desirable.
- Valid driving license.

**TFS Trial Form Support will offer:**

A dynamic and growth-oriented organization with a work environment distinguished by professionalism, integrity and responsibility.

Your job will make a difference!

**For more information about this position please contact:**

Tim Wood, Unit Manager People, Sweden  
Tim.Wood@tfscro.com, 08-587 612 58

We are looking forward to receiving your application with included CV and a personal letter. We practice a continuous selection procedure, so please submit your application via this link <http://www.webforum.com/form/tfsjobb/form.asp?sid=937210991> provided on our website as soon as possible.

