Clinical Research Associate (CRA)

Location: Stirling (FK9 4NF) (office based)

Salary: £COMPETITIVE

Job type: Permanent

Company: The CLINICAL TRIAL Company™

An exciting opportunity has arisen for an experienced Clinical Research Associate (CRA) to join The CLINICAL TRIAL Company™ Ltd (TCTC), a world-leading full-service clinical research organisation (CRO).

TCTC has offices in the UK, Canada, Australia, Singapore and the USA. We operate throughout Europe, North America, South America, India, China, Africa and Australasia. Our expanding company provides clinical trial services and support to the pharmaceutical and medical device sector.

We are seeking an experienced CRA to join The CLINICAL TRIAL Company who will participate in project teams responsible for conducting clinical studies to agreed timelines on behalf of clients, under the supervision of the Project Manager/CRA Manager. This position will report to our CRA Manager based in our head office in Cheshire, UK.

Essential duties and responsibilities include, but are not limited to the following:

- Conducts and documents Pre-Study Visits (PSVs), Study Initiation Visits (SIVs)/Qualification Visits (QVs), Monitoring Visits (MV) and Closedown Visits (CV) as per TCTC SOPs
- To monitor and report on Investigators adherence to approved protocol/amendments and on study conduct at each study site
- To ensure that the Investigator maintains all essential documents and that study related documents, including but not limited to source documents and case report forms, are complete and accurate
- To assist with feasibility studies
- Manage timely compilation and submission of Ethics Applications and assist in Regulatory applications where required
- Conduct telephone calls to investigator sites to evaluate potential patient eligibility and enrolment, and to follow-up on any outstanding issues
- Assist with investigator meetings through the preparation, assembly and shipment of training materials
- Co-ordinate the collection of essential documentation in accordance with ICH/GCP
- Identify, document and report SAEs according to ICH/GCP guidelines and local regulatory requirements, within required timelines and follow-up as required
- Conduct final IMP reconciliation, and arrange return of unused IMPs to the sponsor
- Be responsible for monitoring and maintaining IMP accountability at investigator sites
- Prepare site visit reports and status reports, document site actions in follow up letters/e-mail
- Take telephone calls from team members, investigators and sponsor. Document and follow-up these calls
- Assist Project Manager/CRA Manager with establishing and implementing the query resolution process
- Gain an in-depth understanding of the study protocol, CRF and related procedures
- Develop good working relationships with investigator site personnel and provide support, training and motivation

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- TMF filing and review, as required
- Assist with general project administration
- Be responsible for filing of documentation regarding designated sites
- Adapt protocols/informed consent forms to country specific requirements
- Develop/implement project specific monitoring tools and tracking forms under the direction of the Project Manager/CRA Manager

Description
The role will require you to be educated to degree level or equivalent in a scientific field with proven CRA experience, preferably within a CRO or a pharma company; a full driving licence together with a willingness to travel. The role requires:

- A very strong understanding of the clinical process (particularly Phase II & III) and the ramifications of change to one or more study assumptions including timeline. Previous proposal experience is preferred
- Excellent planning/organizational skills and ability to prioritise and multitask
- Ability to develop effective cross-functional relationships
- Results orientated
- Excellent communication, relationship building and interpersonal skills
- Able to work with autonomy
- Ability to order and prioritise tasks
- Computer Literacy (Word, Excel, PowerPoint, Outlook Express)
- Numeric and budgeting skills
- Good attention to detail

This is an exceptional opportunity within a career driven and progressive organisation offering excellent salaries and benefits.

TCTC offers prospective candidates a truly exciting opportunity to join a growing and dynamic organisation, developing your career as the company grows. TCTC's employees are vital to our success and so we are looking for candidates to join the company and to stay and grow with us. In return you will be rewarded with the opportunity to work on clinical trials of real scientific merit and with excellent opportunities for professional and personal development.

KEY WORDS: Clinical Research Associate; CRA; ICH GCP; Monitor; Monitoring

Before you apply for this position it is vital that you are in possession of an EU or UK passport or relevant visa to work without restrictions in the UK.

For further information on the role please contact:

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Group HR Manager
Email: HR@theclinicaltrialcompany.com
Tel: +44 (0)1565 732 003

Ref: CRA – Stirling

WE ARE SORRY BUT WE DO NOT ACCEPT APPLICATIONS FROM RECRUITMENT COMPANIES