UNIVERSITY OF LEEDS

CANDIDATE BRIEF

Clinical Trial Associate, Faculty of Medicine and Health

Salary: Grade 6 (£26,052 - £31,076 p.a.)

Reference: MHCTR1070

Fixed Funded for 3 years

Clinical Trial Associate
School of Medicine, Clinical Trials Research Unit (CTRU)

Are you an enthusiastic and driven individual with a good working knowledge of Clinical Trials and Good Clinical Practice? Do you want to ensure international quality standards in trial monitoring? Do you want to join a successful, highly talented and multi-disciplinary team in a large, well-established clinical trials unit?

You will be part of the Clinical Trials Research Unit (CTRU) which conducts national and international randomised and early phase clinical trials in a variety of clinical fields, including, cancer, cardiovascular disease and stroke, mental health, obesity, skin, musculoskeletal disease and care of the elderly. Our main aim is to support the challenge of changing clinical practice for the better.

The CTRU particularly specialises in complex phase III trials, efficient phase I/II trials, biomarker driven designs, seamless phase II/III designs, adaptive designs and the development and evaluation of complex interventions. You'll be involved in all stages of the clinical trial, including identifying an investigational site and setting up, initiating, monitoring and closing down the trial, as well as ensuring international quality standards. You will be expected to manage and deliver projects to a high standard.

The role will involve a lot of travelling and you may be out of the office three or four days a week visiting participating centres, occasionally you will also be required to stay overnight. To be successful you will need experience of multi-centre clinical trials in a quality assured clinical trials environment and a working knowledge of the UK regulatory framework. As you will work closely, interactively and collaboratively with a multidisciplinary team of trial coordinators, clinicians and pharmaceutical collaborators you will also need excellent communication skills.

What does the role entail?

As a Clinical Trial Associate, your main duties will include:

- Developing monitoring plans and conducting monitoring visits for your trials and portfolio, in partnership with the Head of Trial Management;



- Ensuring participating sites conduct trials in accordance with applicable GCP Guidelines and regulations, including assisting in obtaining appropriate main ethical and regulatory approval and local approvals;
- Advising on trial protocol content, specifically relating to documentation for use at participating sites within the trial;
- Developing links with other trials units, specifically with their monitoring staff, both national and international;
- Ensuring that safety data is correctly reported to the CTRU by participating sites, to allow the necessary escalation to the regulatory authorities within the timeframes specified by UK law;
- Acting as a key line of communication between investigators, hospital research teams and trial sponsor, conducting site initiations and training;
- Developing, and maintaining, a thorough and up-to-date understanding and working knowledge of the UK Clinical Trial Regulations, EU Directive on Clinical Trials, GCP guidelines and the Research Governance Framework;
- Supervising staff, including monitoring workload and advising upon priorities where required; and
- Presenting research conducted by CTRU at local, national and international conferences.

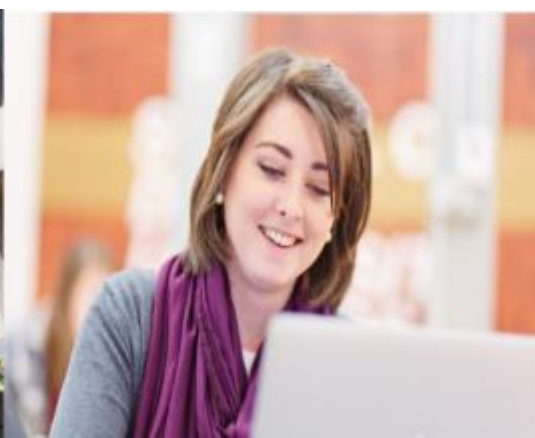
These duties provide a framework for the role and should not be regarded as a definitive list. Other reasonable duties may be required consistent with the grade of the post.

What will you bring to the role?

As a Clinical Trial Associate you will have:

- A BSc, equivalent qualification or considerable relevant experience;
- Experience of multi-centre clinical trials in a quality assured clinical trials environment;
- Working knowledge of Good Clinical Practice, EU Clinical Trials Directive, Medicines for Human Use Act (2004) and the Research Governance Framework;





- Excellent IT skills, including experience using Microsoft Word, Excel and Outlook effectively;
- Strong initiative, with excellent organisational, planning and self-management skills, including the ability to work accurately and carefully, manage and complete projects to deadlines and deliver high quality work;
- Effective communication and interpersonal skills, including written and presentational, with the ability to work and engage with a diverse range of collaborators/stakeholders at all levels;

You may also have:

- A full, valid, current driving license and own transport;
- Experience in the development and implementation of monitoring clinical trials;
- Experience in staff supervision or mentoring;
- Experience of developing standard operating procedures.

How to apply

You can apply for this role online; more guidance can be found on our How to Apply information. Applications should be submitted by **23.59** (UK time) on the closing date.

Contact information

To explore the post further or for any queries you may have, please contact:

Louise Flanagan, Head of Trial Management
Tel: +44 (0)113 343 6441
Email: L.M.Flanagan@leeds.ac.uk



Additional information

You will report to Louise Flanagan, Head of Trial Management.

Find out more about our Clinical Trials Research Unit and our research.

Find out more about the Faculty of Medicine and Health.

Find out more about Athena Swan in the Faculty of Medicine and Health.

Working at Leeds
You can find out more about our generous benefits package and more about what it is like to work at the University and live in the Leeds area in our Working at Leeds information page.

Candidates with disabilities
Information for candidates with disabilities, impairments or health conditions, including requesting alternative formats, can be found in our Accessibility information page or by getting in touch with us at disclosure@leeds.ac.uk.

Criminal record information

Rehabilitation of Offenders Act 1974
A criminal record check is not required for this position, however, all applicants will be required to declare if they have any 'unspent' criminal offences, including those pending.

Any offer of appointment will be accordance with our Criminal Records policy. You can find out more about required checks and declarations in our Criminal Records information page.