UNIVERSITY OF LEEDS

CANDIDATE BRIEF

Clinical Trials Associate, Faculty of Medicine and Health

Salary: Grade 6 (£27,025 – £32,236 per annum)

Reference: MHCTR1158

Closing date: 5 July 2019

Open ended fixed funding for 36 months

We will consider job share and flexible working arrangements (including home based working)

Clinical Trials 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 involved in all stages of a 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 Trials Associate your main duties will include:

- Developing appropriate monitoring plans according to trial risks, planning and conducting site monitoring visits including source data verification and IMP management as required;
- Ensuring participating sites conduct trials in accordance with applicable GCP Guidelines and regulations;
- Advising from a CTA and site perspective on elements of trial delivery including protocol development, data and trial management processes;
- Maintaining a thorough and up-to-date understanding and working knowledge of legislation, guidance and local and national initiatives relating to clinical research and applying this knowledge through working practices on your projects;



- Establishing and maintaining professional relationships with collaborators including sponsor representatives, clinicians, relevant laboratory, pharmacy and research staff at centres participating in specific projects;
- Training and supporting staff at site in accurate and timely data collection and essential document storage;
- Actively contributing to the development of CTRU systems and processes through involvement in Working Groups and development or amendment of associated documentation.

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 Trials Associate you will have:

- A BSc, equivalent qualification or considerable relevant experience;
- Experience of clinical trials in a quality assured environment and experience of clinical or medical data management;
- Working knowledge of Good Clinical Practice, EU Clinical Trials Directive, Medicines for Human Use Act (2004), Data protection Act and the Research Governance Framework;
- A confident manner, inquisitive mind and an ability to constructively participate in complex multi-disciplinary meetings and decision making processes;
- Excellent interpersonal and diplomacy skills, with the ability to build professional working relationships with internal and external stakeholders and work effectively in a team environment, assuming responsibility and making decisions where appropriate;
- Strong initiative, with a high level of organisational, planning and self-management skills, including the ability to work on a range of different tasks simultaneously, manage and meet multiple deadlines and effectively handle or escalate problems;
- A commitment to upholding University values and taking ownership for personal development.



You may also have:

- A full, valid, current driving license and own transport;
- Experience of monitoring clinical trials and conducting site visits;
- 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 page. Applications should be submitted by **23.59** (UK time) on the advertised closing date.

Contact information

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

Emma Armstrong, Regulatory Affairs and Governance Manager
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Anna Hockaday, Head of Trial Management
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Additional information

The Clinical Trials Research Unit within the Leeds Institute of Clinical Trials Research (LICTR) is an international leader in the field of clinical trials. The Unit is one of the largest in the UK and conducts national and international randomised and early phase clinical trials in a variety of clinical fields. Our main aim is to support the challenge of changing clinical practice for the better and our past results and current work have already helped to do this. Our results inform the academic development of this specialised field of clinical research on a national and international level. Particularly, we specialise 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.



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
Find out more about the benefits of working at the University and what it is like to live and work in the Leeds area on 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 on 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 in accordance with our Criminal Records policy. You can find out more about required checks and declarations in our Criminal Records information page.