UNIVERSITY OF LEEDS

CANDIDATE BRIEF

Senior Clinical Trial Manager, Leeds Institute of Clinical Trials Research

Salary: Grade 7 (£35,333 – £42,155 p.a. dependent upon experience)

Reporting to: Head of Trial Management

Reference: MHCTR1260

100 FTE (part time hours considered)

36m Open Ended Fixed Funding, due to external grant funding

Overview of the Role

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.

You will join our team and take responsibility for coordinating specific clinical trials from set-up and recruitment through to trial closure and analysis. You will directly co-ordinate large multi-centre trials and/or lead a CTRU portfolio trial management team, ensuring international quality standards in trial management for the projects/portfolio by supervising complex trials and associated trial co-ordination staff across the therapeutic area. You will also support the dissemination of research results by contributing to high quality publications and presenting at meetings and conferences.

Main duties and responsibilities

As a Senior Clinical Trial Manager your main duties will include:

- Leading the set-up, conduct and closure of multi-centre randomised controlled trials and actively contribute to the design, from a trial co-ordination, regulatory and logistics perspective;
- Managing projects, making of day-to-day decisions and highlighting critical issues to the senior team, adhering to milestones and resources outlined in the grant application and supervising and managing trial co-ordination staff;
- 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 the projects you manage;
- Working in partnership with the Divisional Director, Principal Statistician and Head of Trial Management to develop grant applications and implement high quality randomised controlled trials;



- Establishing and maintaining professional relationships with collaborators including funders, staff from other trials units, clinicians, professors, relevant laboratory and research staff at both national and international centres;
- Actively contributing to the development of systems and processes through involvement in Working Groups and development or amendment of associated documentation;
- Contributing to high quality publications in peer-reviewed clinical and methodological journals and presenting research, and/or issues in trial design and conduct, at local, national and international meetings and conferences;
- Delivering relevant training sessions, both internally and externally.

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.

Qualifications and skills

Essential:

- Substantial experience in Trial Management of interventional trials in a quality assured clinical trials environment or substantial experience of leading and implementing research across several organisations
- Knowledge of the regulatory and governance environment in the UK and other relevant guidance, for example Consolidated Standards of Reporting Trials CONSORT, and experience of implementing within projects
- Confidence, experience and the ability to lead and participate constructively in complex multi-disciplinary meetings and decision-making processes with strategic thinking and an inquisitive mind
- Previous experience supervising or line managing people, with the ability to work effectively in a team assuming responsibility, leading projects and making decisions within the sphere of the role
- The ability to build professional working relationships with internal and external staff, using with effective negotiation, diplomacy and influencing skills



It would be desirable to also have:

- Experience of trial management within a relevant area; Clinical Trials of Investigational medicinal Products CTIMP, surgery, device or Complex intervention.

Key Attributes

- Excellent communication and interpersonal skills, along with the ability to manage and meet deadlines.

Additional information

Find out more about the Faculty of Medicine and Health.

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

Find out more about our Institute Leeds Institute of Clinical Trials Research.

Working at Leeds
We are a campus-based community and regular interaction with campus is an expectation of all roles in line with academic and service needs and the requirements of the role. We are also open to discussing flexible working arrangements. To find out more about the benefits of working at the University and what it is like to live and work in the Leeds area visit our Working at Leeds information page.

Our University
As an international research-intensive university, we welcome students and staff from all walks of life. We foster an inclusive environment where all can flourish and prosper, and we are proud of our strong commitment to student education. Within the Faculty of Medicine and Health we are dedicated to diversifying our community and we welcome the unique contributions that individuals can bring, and particularly encourage applications from, but not limited to Black, Asian, people who belong to a minority ethnic community; people who identify as LGBT+; and disabled people. Candidates will always be selected based on merit and ability.



Information for disabled candidates
Information for disabled candidates, impairments or health conditions, including requesting alternative formats, can be found on our Accessibility information page or by getting in touch with us at hr@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 subject to the University being satisfied with the outcome of these checks, in accordance with our Criminal Records policy. You can find out more about required checks and declarations in our Criminal Records information.

Please note: If you are not a British or Irish citizen, from 1 January 2021 you will require permission to work in the UK. This will normally be in the form of a visa but if you are an EEA/Swiss citizen and you were resident in the UK before 31 December 2020, this will be your status under the EU Settlement Scheme.