UNIVERSITY OF LEEDS

CANDIDATE BRIEF

Senior Clinical Trial Data Manager (Pharmacovigilance Lead)
Faculty of Medicine and Health

Salary: Grade 7 (£33,199 – £39,609 per annum)

Reference: MHCTR1168

Closing date: 13 October 2019

Fixed-term for 36 months

Senior Clinical Trial Data Manager – Pharmacovigilance Lead
School of Medicine
Clinical Trials Research Unit (CTRU)

Do you have considerable experience of clinical trial data management and pharmacovigilance? Do you have excellent organisational and communication skills? Do you want to be part of a leading team that has a national and international reputation for excellence in conducting complex, multi-centre clinical trials?

The Clinical Trials Research Unit (CTRU) 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.

You will join our team and take responsibility for the management of safety data for a portfolio of specific clinical trials from set-up and recruitment through to trial closure and analysis. You will lead on the management of safety data directly on large multi-centre trials and lead a centralised pharmacovigilance team, ensuring international quality, patient safety and regulatory standards across the studies. You will contribute to the development of new research projects and may be involved in dissemination of research results by contributing to high quality publications and presenting at meetings and conferences.

You will have experience of data management and pharmacovigilance gained working on interventional clinical trials. You will also have up-to-date knowledge of legislation, regulatory and governance environment relating to data management, pharmacovigilance and clinical trials. You will also act as a contact point for advice and support on pharmacovigilance issues and provide training in pharmacovigilance and related matters across the wider Institute.



As you will work closely, interactively and collaboratively with multiple stakeholders you will need excellent communication and interpersonal skills, along with the ability to manage and meet deadlines.

What does the role entail?

As a Senior Clinical Trial Data Manager - Pharmacovigilance lead, your main duties will include:

- Planning for and managing safety data for a portfolio of projects, making of day-to-day decisions, advising on and adhering to milestones and resources outlined in the grant application and supervising and managing a team of safety data management staff;
- Implementing appropriate systems to ensure that safety data is recorded, handled, and stored in a way that allows its accurate and timely reporting, interpretation and verification;
- Contributing to the trial risk assessment and taking a risk-based approach to collection of safety data, implement monitoring strategies appropriate to the specifics of each trial and escalating any critical issues to the senior team;
- Maintaining a thorough and up-to-date understanding and working knowledge of legislation, guidance and local and national initiatives relating to clinical research and management of safety data and applying this knowledge through working practices on the projects you manage; ensuring compliance with regulatory requirements in respect to pharmacovigilance.
- Working in partnership with the Divisional Director (s), Principal Statistician and Head of Trial Management to 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 and regulatory authorities;
- Actively contributing to the development of systems and processes through involvement in or leading Working Groups and development or amendment of associated documentation and provision of advice and training; particularly with respect to pharmacovigilance.
- 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.

What will you bring to the role?

As a Senior Clinical Trial Data Manager (pharmacovigilance lead) you will have:

- Substantial experience in Data Management and pharmacovigilance of interventional trials in a quality assured clinical trials environment;
- 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;
- The ability to assimilate information and reproduce it in a clear, consistent, accurate and relevant manner according to purpose and audience;
- 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 effective negotiation, diplomacy and influencing skills;
- A high level of organisational, planning and self-management skills, including the ability to manage and meet multiple deadlines and deliver projects across several organisational boundaries and handle problems, efficiently and effectively, using own initiative;
- A commitment to upholding University values and taking ownership for personal development.

You may also have:

- Experience designing and delivering training sessions in a relevant area; pharmacovigilance or data management



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:

Anna Hockaday, Head of Trial Management
Tel: +44 (0)113 343 7682; Email: a.m.chalmers@leeds.ac.uk

Additional information

Find out more about the Clinical Trials Research Unit.

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's 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.