UNIVERSITY OF LEEDS

CANDIDATE BRIEF

Clinical Trials Associate, Faculty of Medicine & Health

Salary: Grade 6 (£27,511 – £32,817 p.a.)

Reference: MHLRM1128

Closing date: 4 February 2020

Clinical Trials Associate
Leeds Institute of Rheumatic & Musculoskeletal Medicine
School of Medicine

Do you have experience of monitoring clinical trials and excellent organisational skills? Do you have effective communication skills with a positive approach and the ability to multi-task? Would you like to join a team supporting senior academic staff and actively promote Good Clinical Practice?

We are looking for a professional and proactive individual to join our team who can bring their excellent organisational skills to the support of the rheumatology research teams including senior academics, clinicians, nurses and administrative staff at Chapel Allerton Hospital.

You will have experience of working in a busy office environment with strong communication and interpersonal skills. You will also have the skills to manage a busy workload, often working with autonomy, with the ability to multi-task and work to a high level of accuracy.

The Leeds Institute of Rheumatic & Musculoskeletal Medicine (LIRMM) conducts clinical trials covering a number of musculoskeletal diseases, many using investigational medicinal products. We are looking for a Clinical Trial Associate to join our team to undertake all aspects of study monitoring primarily for our in-house drug trials. You will be based at Chapel Allerton Hospital to provide an efficient monitoring service, actively reviewing the set-up, conduct and closure of trials, as defined by the EU Clinical Trials Directive and Good Clinical Practice guidelines. Knowledge of the UK regulatory framework is essential.



What does the role entail?

As a Clinical Trials Associate your main duties will include:

Research Management and Trial Conduct

- Acting as a member of the trials administrative team, working closely with the MSK Trial Management Lead, Clinical Trials Coordinators, Research Nurses, Database Developer, Principal Investigators, LIRMM Business Manager and Sponsor QA team;
- Supporting the administrative team and department prior to any inspection from the UK regulator, the MHRA, or any other external audits;
- Contribute to the writing of monitoring plans for in-house studies and liaising with the Sponsor QA department;
- Conducting monitoring visits in accordance with the agreed monitoring plan for the trial and establishing and maintaining systems to track progress of monitoring visits and their required actions;
- Oversight of the progress of trials, including site recruitment, adherence to the protocol, data collection and data quality and ensuring the accuracy, consistency and completeness of data;
- Discussing issues identified with the PI and study team or raising them at team meetings or committee meetings;
- Producing regular trial monitoring reports for the operational group, and Research Oversight Committee (ROC) for which you will be a core member and other groups as required, including highlighting significant findings, deviations and deficiencies and to support resolution of the recommended actions;
- Where applicable using the relevant computer software to process source data queries and identify problems and discuss these with the project team;
- Advising on the content and layout of case report forms (CRF or eCRF) to ensure they are clear, well designed and user friendly;
- Assisting with user acceptance testing for any new data collection database and the QMS Database Development team;
- Highlighting issues to the trial team to help them to identify any amendments needed as the trial progresses and ensuring the team are aware of current version control;



- Following the appropriate security measures to prevent unauthorised access to patient-named data in accordance with the Data Protection Act;
- Liaising and supporting local investigators and research staff on issues relating to trial progress, protocol violations and GCP or any suspected serious breaches;
- Establishing professional relationships with staff from clinical trials units, clinicians, Professors, and relevant laboratory and research staff at both national and international centres participating in specific studies.

Quality Assurance and Regulation

- Supporting colleagues and the department in maintaining trial standards to meet regulatory requirements such as preparation for external regulatory inspection by the MHRA or internally by the Sponsor i.e. monitoring or audit;
- Maintaining a thorough understanding and working knowledge of the UK Clinical Trial Regulations, EU Directive on Clinical Trials, ICH-GCP guidelines and the UK Policy Framework for Health & Social Care, and develop experience of applying this knowledge through working practices, development of trial specific SOP's relating to monitoring functions and liaising with the Sponsor QA department;
- Sit on the feasibility committee (CAH CSU) as a core voting member;
- Taking authorship responsibilities for writing and/or updating SOPs and guidance documents;
- Reviewing and approving trial specific documents such as monitoring work instructions and site-specific guidance documents;
- Ensuring participating sites conduct the trial in accordance with applicable GCP guidelines and regulations.

Administration

- Assisting project teams to meet tight deadlines, such as collection of information for interim and final analyses.

Specialist Role

- Act as internal lead for the training of staff by delivering specialist learning bursts and other bespoke training needs as required by the department;
- Developing specialist knowledge within rheumatology and musculoskeletal disease;

- Understanding of medical devices may be required to monitor other LIRMM trials such as dermatology or trauma and orthopaedic studies;
- Maintaining knowledge of trial monitoring and practical experience of applying this knowledge through active study set-up, recruitment and close-out;
- Keeping up to date with current research relevant to each project and keeping informed of research in clinical trial monitoring.

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.

You will report to James Goulding, MSK Trial Management Lead.

What will you bring to the role?

As a Clinical Trials Associate you will be:

- Educated to degree level in a relevant subject (or equivalent qualification/experience);
- Experience of working as a Clinical Trials Associate within academia or industry;
- Proven experience and understanding of the requirements needed to monitor single or multi-centre clinical trials in a quality assured clinical trials environment;
- Excellent knowledge of ICH-GCP, EU Clinical Trials Directive, Medicines for Human Use Act (2004) and the UK Policy Framework for Health & Social Care;
- Familiarity with medical terminology;
- Competent in the use of Microsoft Office (Word-processing, spreadsheet and database packages);
- Experience of working within a busy office environment;
- Excellent communication and interpersonal skills, including written and presentational;
- Excellent attention to detail;
- Effective organisational and time management skills;
- Experience of working both within a team and ability to work independently, being able to use initiative and apply knowledge to practical situations.



You may also have:

- Knowledge and experience of commercial clinical trials and other trials i.e. non-CTIMPs i.e. device trials;
- Experience of monitoring within the Pharmaceutical Industry, CRO or an academic Clinical Trials Unit;
- Experience of preparing for MHRA inspection and responding to MHRA findings & CAPA plans;
- Understanding of clinical trial design and feasibility issues.

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.

Interviews are anticipated to take place on:

Contact information

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

James Goulding, MSK Trial Management Lead
Tel: +44 (0)113 39 24396
Email: j.t.r.goulding@leeds.ac.uk

Additional information

Find out more about the Faculty of Medicine and Health

Find out more about Athena Swan in the Faculty.

Find out more about our Institute within the Faculty.

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.