UNIVERSITY OF LEEDS

CANDIDATE BRIEF

Data Manager, Faculty of Medicine and Health

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

Reference: MHCTR1167

Closing date: 29 September 2019

Open ended fixed funding for 36 months

We will consider job share and flexible working arrangements

Data Manager
School of Medicine, Clinical Trials Research Unit (CTRU)

Are you an enthusiastic and driven individual with a good working knowledge of Clinical Trials (or similar large studies) and Data Management? Do you want to ensure quality standards in data collection to provide reliable answers to key research questions for patient benefit? Do you want to join a successful, highly talented and multi-disciplinary team in a large, well-established clinical trials unit?

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.

You will join our team and take responsibility for the data management of specific clinical trials from set-up and recruitment through to trial closure and analysis. This will involve the collection, computerisation and validation of data, creating trial specific database specifications and supervising data management staff.

You will have experience of data management, ideally gained working on interventional trials along with an up-to-date knowledge of legislation, regulatory and governance environment relating to clinical trials. As you will work closely, interactively and collaboratively with numerous stakeholders you will need excellent communication, interpersonal and team working skills, along with the ability to manage and meet deadlines.



What does the role entail?

- Co-ordinating the set-up, conduct and closure of multi-centre randomised controlled trials, and contributing to the design, conduct and analysis from a data collection and data management perspective. This will include development and maintenance of appropriate data collections methods and writing the relevant sections of the protocol, CRF design, database specification and testing, identification and implementation of appropriate database reports to facilitate trial monitoring;
- Managing and coordinating the data management of projects on a day-to-day basis to deliver a reliable and complete dataset, meeting agreed milestones, providing appropriate updates and reports relevant to specific meetings groups, highlighting issues for further discussion with the senior project team and supervising and managing data management staff working on the projects;
- 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 clinicians, professors, relevant laboratory and research staff at centres participating in specific projects;
- Actively contributing to the development of CTRU systems and processes through involvement in Working Groups and development or amendment of associated documentation;
- Delivering relevant training sessions internally within the Unit and externally for site staff responsible for data collection.

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 Data Manager you will have:

- Experience in data management in interventional trials in a quality assured clinical trials environment or substantial experience of managing large clinical or medical datasets collected from multiple organisations;
- Expertise in designing case report forms or equivalent and specifying database requirements for the accurate collection of medical data;
- Knowledge of the regulatory and governance environment in the UK and other relevant guidance, for example Consolidated Standards of Reporting Trials (CONSORT), and the practical application within projects;
- A confident manner and inquisitive mind and ability to constructively participate in complex multi-disciplinary meetings and decision making processes;
- The ability to assimilate information and reproduce it in a clear, consistent and accurate manner, tailoring it to suit purpose and audience;
- 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; and
- A commitment to upholding University values and taking ownership for personal development.

You may also have:

- Experience of data management within a relevant area, such as Clinical Trials of Investigational medicinal Products (CTIMP), surgery, device or complex intervention.



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:

Suzanne Hartley, Head of Trial Management
Tel: +44 (0)113 343 8041
Email: s.hartley@leeds.ac.uk

Additional information

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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.