UNIVERSITY OF LEICESTER

Job Summary

Job Title: Senior Trial Manager
Grade: 7
Salary: £38,205 to £44,263 per annum
Department: Leicester Clinical Trials Unit (LCTU)
Hours/Contract: Full-time fixed term contract for two years
Job Family: Management and Administration
Reference: 10010

Role Purpose

Reporting to the Head of Trial Management, you will be responsible for the management of large multi-centre randomised controlled trial(s) and overseeing a portfolio of trials. You will provide leadership and line management of a small team of trial managers/coordinators. You will be expected to work independently but also part of the wider team, working closely with LCTU senior management, and collaborating with NHS clinical and academic staff. You will provide trial management expertise to maintain the smooth and effective running of your portfolio of clinical trials and research studies in accordance with the study protocols, ethics and regulatory approvals, SOPs, GCP principles, EU Directives and UK legislation.

Main Duties and Responsibilities

- Accountable to the Head of Trial Management, providing leadership and trial management expertise in order to develop, organise and facilitate a portfolio of clinical trials. This includes ensuring trials are conducted in accordance with the appropriate SOPs, regulations and ethical approvals.
- Be responsible for the oversight, management and delivery of a trial management team, including trial managers, co-ordinators and trial administrators (as appropriate). Motivate your team and provide day-to-day supervision, coaching and operational direction. Monitoring trials performance against project management plans, using various online tools and proactively solve problems, taking appropriate action where necessary to ensure timelines are met.
- Providing key input to grant applications, protocols, case report forms design and remote data entry systems and all associated documentation. Assisting Chief Investigators to ensure timely sponsor, regulatory, ethical and HRA approvals. Responsible for the creation and maintenance of Trial Master Files and Investigator Site Files ensuring all participating sites have current trial information.
- Set up participating sites by undertaking site initiation visits, remotely and/or in person as necessary. Identify and undertake feasibility of sites, ensuring all participating sites have received relevant trial specific training. Facilitating approvals in order for sites to open to recruitment. Monitoring performance and progress of each trial site and take appropriate action.
- Contribute to the CTU quality management system, reviewing and writing SOPs and developing procedural documentation as applicable. Ensure that practice adheres to relevant University policies and procedures.

- Prepare standard operating procedures for the running of individual clinical trials to ensure research complies with current legislation. To coordinate and support the activities of the Trial Management Group, Trial Steering and Data Safety Monitoring Committees.
- Working with the LCTU Database Development Manager, Principal Statistician and Quality Manager contributing to and implementing data management and trial monitoring plans. Incorporating appropriate risk assessments and appropriate mitigations in the running of all trial's activity.
- To coordinate communications among all trial stakeholders including trial research team, funding bodies, sponsor, collaborative groups and participating sites, ensuring a common understanding of trial progress.
- Plan expenditure against trial budgets and monitor the budget for the portfolio of trials the post has responsibility for. Drive the procurement process for suppliers according to UoL policies, where necessary. Prepare trial progress and/or financial reports as required by the LCTU and College senior management teams, funding bodies, regulatory authorities, ethics committees, Investigators, trial Steering and Data Monitoring Committees, funding bodies and external collaborators.
- As part of the wider LCTU, drive and support necessary change in order to optimise the operations of the LCTU and proactively contribute to its continued growth.
- To represent the LCTU at external conferences/meetings and undertake any other relevant duties as required by the Head of Trial Management.

Internal and External Relationships

The post-holder is expected to deal effectively with a wide range of individuals including:

Internal

- Daily - trial management and monitoring personnel, IT and data management staff, administration and finance staff, other senior trial managers and statisticians in the CTU.
- Regular – senior LCTU staff and Director, internal sponsor offices, internal senior investigators, academics and clinicians.

External

- Daily – external investigators, academics and trial teams, external sponsors.
- Regular – funders, Clinical Research Networks, Regulatory Agencies, other NHS Trusts and Institutions, and Industry.

Planning and Organising

- Manage own workload and oversee the management of trial teams the post holder is responsible for.

  Take overall responsibility for trial management in compliance with regulatory guidelines. Maintain up-to-date knowledge of regulatory, ethical and governance requirements and

translate this into practical activities.

- Effective workload and project planning of own trial activities and those of direct reports: set and ensure that quality control procedures are in place for all aspects of the trial, to maintain and improve operational efficiency and quality by development and application of process improvements. Plan work activities against the agreed quality standard and team objectives, to ensure operational quality and efficiency. Adjust priorities as needed. Be able to recognise circumstances that require the involvement of Head of Trial Management.
- Coordinate and oversee the multicentre trial(s) through effective communication with research staff in trial sites and the networks, collaborators, the trial steering committee, and other members of the trial team, representing the CTU in a professional manner.
- Manage the day-to-day running of the trial(s) by establishing standardised procedures that ensure compliance with the protocol and regulatory standards, monitoring compliance, and taking decisions on actions required.

Qualifications, Knowledge and Experience

Essential

- A higher degree (PhD or MSc) in a relevant biomedical science or associated subject with experience of clinical trials research, particularly CTIMPs* OR
- A graduate with experience in a Trial Management environment, in particular delivering CTIMPs* OR
- An in depth understanding of clinical research and trial management methodology, including applicable regulatory requirements, and a proven ability to apply these to the coordination of clinical trials, particularly CTIMPs*
- Experience preparing the following: regulatory and ethics submissions, grant applications, writing and/or amending protocols, patient information sheets, Case Report Forms, reports and other relevant trial management documentation*

Desirable

- Experience of generating SoECATs to the point of approval
- Experience of delivering Trial Management for a CTIMP oncology trial
- Experience preparing publications and submitting grant applications
- Experience of writing SOPs either for trials or within a CTU
- Experience of data management
- Experience of Kanbanchi or other similar project management tools
- Ability to travel locally and nationally

Skills, Abilities and Competencies

Essential

- Proven project management and line management skills*

- Effective communication, negotiation, presentation and interpersonal skills, including team leadership and motivation*
- Must demonstrate a critical and intelligent attention to detail and high standards of accuracy*
- Excellent computing skills including email, spreadsheets, word processing, databases, internet and working knowledge of MS office suite
- Able to work on own initiative and problem solve as well as collaboratively as part of a team

Criteria to be used in shortlisting candidates for interview

Reason for Fixed Term Contract

The reason for the fixed term contract is stated in section 1.9 in the summary of contractual terms in your contract of employment.

Criminal Declaration

If you become an employee, you must inform your manager immediately, in writing, if you are the subject of any current or future police investigations/legal proceedings, which could result in a criminal offence, conviction, caution, bind-over or charges, or warnings.

Supporting University Activities

As a University of Leicester citizen, you are expected to support key university activities such as clearing, graduation ceremonies, student registration and recruitment open days. We expect all staff as citizens to work flexibly across the University if required.

University Values

Inclusive - We are diverse in our makeup and united in ambition. Our diversity is our strength and makes our community stronger.

Inspiring - We are passionate about inspiring individuals to succeed and realise their ambitions. We challenge our community to think differently, to get involved, and to constantly embrace new ideas.

Impactful - As Citizens of Change we will generate new ideas which deliver impact and empower our community

Equity and Diversity

We believe that equity, diversity and inclusion is integral to a successful modern workplace. By developing and implementing policies and systems that challenge stereotypes across all aspects of our work, we have a culture that recognises and values the diverse contributions of our staff which benefits everyone. Our strong values of inclusivity and equality support our efforts to attract a diverse range of high quality staff and students, and identify our University as a progressive and innovative workplace that mainstreams equality, diversity and inclusion.

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