UNIVERSITY OF LEICESTER

Job Summary

Job Title: Trial Manager
Grade: 6
Salary: £31,396 to £36,024 per annum
Department: Leicester Clinical Trials Unit (CTU)
Hours/Contract: Full-time, or job share considered, fixed term contract for 18 months
Job Family: Management and Administration
Reference: 9929

Role Purpose

Reporting to a Senior Trial Manager, the post-holder will be responsible for managing and overseeing one or more complex CTIMP/non-CTIMP, multi-site trials, including the performance and line management of trial coordinators and/or trial administrators.

The post-holder will be responsible for the initiation, organisation and administration of the trial(s), working under the direction of CTU senior managers and the trial Chief Investigator. The post-holder will be expected to work pro-actively as part of a wider team of NHS clinical and academic staff to ensure the highest standards of research governance, and to deliver the trials on time and to budget. They will provide trial management expertise to maintain the smooth and effective running of all research studies in accordance with the trial protocols, ethical and regulatory approvals, SOPs, the principles of GCP and applicable EU Directives and UK legislation.

The post holder must be able to use their own initiative, be an effective leader, team player and excellent communicator.

Main Duties and Responsibilities

- To be a proactive contributing member of the multi-disciplinary team accountable to the Chief Investigator and Senior Trial Manager, developing and running multi-centre randomised CTIMP/non CTIMP clinical trials and other research studies. To be the key contact for specific trials and to coordinate and support the activities of the Trial Management Group, Trial Steering and Data Monitoring Committees. To undertake site initiation visits throughout the UK, produce trial specific guidance notes, provide training, identify problems and seek solutions, and provide support to research staff on the practical implementation of GCP and on trial related activities, taking appropriate action to enable staff to carry out their respective trial duties and tasks. This requires regular liaison with clinicians, database developers, statisticians, research nurses, and other personnel, across the UK and sometimes overseas, monitoring progress of each trial site and taking appropriate action to ensure adherence to the protocol. To inform and motivate trials staff by writing newsletters, updating web pages, organising investigator or trial management meetings, and holding training sessions.
- To undertake quality checks and assurance audits to maintain trial quality, highlighting any deviations for further relevant action.
- Take responsibility for ensuring that trial research data is complete and accurate. To write Data Management and Validation plans for the trials, ensuring they are followed and all data validations/checks are undertaken, either by themselves or other staff members. Decide what steps need to be taken to correct any missing, contradictory or incorrect data and ensure that

this is resolved within a reasonable timescale. In consultation with the trial statistician, database developers and quality team.

- Ensure timely regulatory and ethical approvals for clinical trials including trial sponsorship and HRA authorisations (including REC and MHRA approvals). Ensure Standard Operating Procedures for safe trial conduct are followed (e.g. reporting of adverse events to regulatory authorities and Data Monitoring Committees); and prepare standard operating procedures for the running of individual clinical trials to ensure that the research complies with current legislation.
- To undertake trial risk assessments and devise quality assurance plans in line with LCTU processes.
- Be responsible for management of junior data/trial co-ordinator and administration staff with respect to day-to-day supervision of: trial set-up and delivery, workload allocation, motivation and support (including training and development, cover rotas, problem solving, appraisals and monitoring performance).
- Reporting on performance and progress of each trial site and take appropriate action to ensure good recruitment, compliance with the protocol, the quality and timeliness of the data collection. Use initiative to tackle any practical difficulties reported by clinical sites, i.e. which affect recruitment, protocol adherence or patient safety. Conduct problem solving/ quality assurance monitoring visits as required.
- Prepare general, trial and finance progress reports as required by the LCTU and study teams, management teams, funding bodies, regulatory authorities, ethics committees, Investigators, Trial Steering and Data Monitoring Committees, funding bodies and external collaborators.

Internal and External Relationships

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

Internal

Daily - trial and data teams, monitoring personnel, IT and database staff, administration and finance staff, senior trial managers and statisticians.

Regular – senior LCTU staff and Directors, 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

- 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 without reference to others: set and ensure that quality assurance procedures are followed for all aspects of the trial to maintain and improve operational efficiency and quality by development and application of process improvements.

Plan own 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 senior trial managers or chief investigators

- Coordinate and oversee trial 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 by establishing standardised procedures that ensure compliance with the protocol and regulatory standards, monitoring compliance, and taking decisions on actions required. This requires a high degree of organisation with good attention to detail including high standards of accuracy and an ability to forward plan with prioritisation of tasks and workload to ensure trial deadlines are met. Train and/or supervise trial personnel, setting day-to-day or study-specific targets as applicable, and evaluating progress and performance against objectives. Monitor the trial budget, advising the CTU senior managers.

Qualifications, Knowledge and Experience

Essential

- A degree (BSc/FdSci) or equivalent experience in a relevant biomedical science or associated subject with experience of clinical trials research*
- An 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*
- Experience preparing one or more of the following: regulatory and ethics submissions, grant applications, writing and/or amending protocols, patient information sheets, Case Report Forms*
- Proven project management and line management skills*

Desirable

- Experience in the interrogation of complex databases (Macro preferred or equivalent)*

Skills, Abilities and Competencies

Essential

- Excellent administrative, clerical and office management skills
- Effective communication, negotiation, presentation and inter-personal skills
- Excellent computing skills including advanced word processing and email.
- Able to work on own initiative and problem solve
- Must demonstrate a critical and intelligent attention to detail and high standards of accuracy*
- Ability to travel locally and nationally*

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.

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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.
Equality and Diversity
We believe that equality, 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.