UNIVERSITY OF LEICESTER

Job Summary

Job Title: Clinical Trial Manager
Grade: £33,002 to £37,694 per annum, pro rata
Salary: 6
Department: Cardiovascular Sciences
Hours/Contract: Part-time (0.6FTE, 22.5 hours per week) fixed term contract for 24 months
Job Family: Management and Administration
Reference: 12796

Role Purpose

We are looking for a Clinical Trial Manager to help deliver the ACCELERATE-CMR trial. This is a multi-centre clinical trial of a new, fast magnetic resonance imaging (MRI) scan to help improve the care of people with suspected coronary heart disease. A standard cardiac MRI scan takes 45-50 minutes, which many people find too long and uncomfortable. The new scan takes around 20 minutes. This trial will establish whether the new scan is as good as the longer scan: if so, it could transform clinical care, improving efficiency and shortening waiting lists.

You will play the leading role in planning, co-ordinating and completing this trial.

Reporting to the Chief Investigator and working closely with the Cardiovascular Research Manager, you will be expected to work independently but also as part of the wider team working closely with clinical and academic staff. Previous experience in the management and co-ordination of clinical trials is desirable but not essential; however, appropriate academic and/or vocational qualifications are necessary.

Please note that for this role, we would expect the successful candidate to send at least 0.4 FTE in the office, based at the Glenfield Hospital, with the other 0.2FTE flexible/working from home.

Main Duties and Responsibilities

Daily operational running of the ACCELERATE-CMR trial. This will include but is not limited to:

- Oversee the day-to-day running of the ACCELERATE-CMR trial. Principle responsibility for setting up the study (writing protocols, ethics approvals, study amendments) and measuring the trial's performance against project management plans, and taking appropriate action where necessary to ensure timelines are met.
- To be a leading member of the research team, accountable to the Chief Investigator and Cardiovascular Research Manager, providing leadership and trial management expertise in order to develop, organise and facilitate this clinical trial. This includes ensuring the trial is conducted in accordance with the appropriate UoL SOP's, regulatory, and ethical approvals.
- Providing input into case report form designs, study data collection and associated systems, data management, analysis and interpretation
- Managing study documentation according to strict national and local research governance regulations and protocols.
- Organise, facilitate and document meetings and other communications of the trial members, partners, funding bodies, and sponsor.

- Preparation of research reports, papers and presentations including maintaining oversight of the budget, expenditure and providing general finance support;
- Contribute to research protocol development and preparation of funding applications;
- Contribute to the IRAS application process for new clinical studies, and amendments to existing ones;
- Supervision and support of other research staff and students;
- Attend and contribute to team, departmental and partner meetings and seminars; co-ordinate and support the activities of Trial Management, Trial Steering, and Data Safety Monitoring Committees.
- Engagement in relevant professional activities and continuous professional development.

Internal and External Relationships

- Liaison with external collaborators particularly the University Hospitals of Leicester NHS Trust, the Leicester Biomedical Research Centre, Glasgow Clinical Trials Unit, and other trial collaborators
- Working with research team, research fellows, NHS staff, patients and relevant stakeholder groups

Planning and Organising

You will be required to effectively manage your time to plan your research activity and to deliver on the priorities of the trial:

- Prioritise tasks within agreed work schedules;
- Plan for specific aspects of research incorporating issues such as deadlines, project milestones, and overall research aims;
- Adapt daily and weekly plans to accommodate new developments and be flexible to the changing priorities of the project;
- This will include travel between university, hospital, and research sites.
- Maintain up- to-date knowledge of regulatory, ethical, and governance requirements, and translate this into practical activities.
- Be able to recognise circumstances that require the involvement of senior staff.
- Attend suitable training courses or equivalent and be proactive in terms of continued professional development

Qualifications, Knowledge and Experience

Essential

- Degree in subject relevant to research subject *
- Evidence of experience working as a health and / or research professional (typically ~4 years)*
- Familiarity with clinical trial design, delivery and regulatory requirements *

- Experience of preparing one or more of 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*
- Experience of working on a multi-centre trial*
- Sound understanding of the principles of NHS research ethics

Desirable

- Experience of interacting with patients in research studies*
- Experience of working in a healthcare environment*
- Experience of remote recruitment methods*
- Experience of supervising junior members of staff
- Experience of monitoring research in a commercial and non-commercial environment
- Experience of writing SOPs for trials
- Experience of data management

Skills, Abilities and Competencies

Essential

- Sound IT skills (e.g. Microsoft Office)*
- Excellent written communication skills*
- Experience in the coordination of multi-centre studies *
- Excellent verbal communication skills *
- Evidence of working both independently and as part a team *
- Able to work to high standards of professionalism, confidentiality, health and safety, and respect for study participants
- Excellent organisational and time management skills
- A high level of accuracy and attention to detail*

Desirable

- Excellent presentation and scientific writing skills;
- Understand, interpret and critically analyse data and information and prepare progress reports

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 and Disclosure and Barring Service (DBS).

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.

This post is exempt from the Rehabilitation of Offenders Act 1974 because the appointee will have substantial access to young people and/or vulnerable adults. Therefore, an appointment to this post will be subject to checking through the Disclosure and Barring Service (DBS). The successful applicant for this post will, therefore, be required to give consent for the University to check and obtain appropriate clearance with the DBS for the existence and content of any criminal record in the form of a Standard Disclosure.

Information received from the DBS and the police will be kept in strict confidence and will be destroyed once the University is satisfied in this regard.

NHS Research Governance

Where it is determined that the duties of this post for the purposes of research involve work with the NHS, it is necessary to ensure that the performance of the duties attached to the post are covered by NHS research governance arrangements and the appointee must comply with all such arrangements, which may include occupational health clearance and DBS clearance.

Supporting University Activities

As a University of Leicester citizen, you are encouraged to support key university activities such as clearing, graduation ceremonies, student registration and recruitment open days. We encourage all staff as citizens to work flexibly across the University if required. If supporting these activities is likely to affect your workload, please speak to your line manager in the first instance

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

Freedom of Speech

The University is committed to upholding freedom of speech and academic freedom within the law throughout our recruitment processes. We ensure that all candidates are considered based on merit and suitability for the role, without regard to their lawful viewpoints or the expression of challenging or controversial ideas. Our recruitment policies and practices are designed to protect applicants from discrimination or adverse treatment on the basis of their opinions, and to foster an environment where open debate and diverse perspectives are valued as essential to our academic mission.

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.