UNIVERSITY OF LEICESTER

Job Summary

Job Title: Trial Manager (Electrophysiology)
Grade: 6
Salary: £32,546 to £37,174 per annum pro rata
Department: Cardiovascular Sciences
Hours/Contract: Part-time (0.6FTE, 22.5 hours per week), fixed term contract until 30 September 2026
Job Family: Management and Administration
Reference: 11961

Role Purpose

You will support the Electrophysiology Research Group (EpRG) led by Professor G Andre Ng, helping to manage multiple studies within the research portfolio. These will include LifeMap QUEST, an NIHR i4i-funded clinical study to confirm the safety and tolerability of a device developed by the group to reduce noise and optimize ECG signal during exercise to help stratify Sudden Cardiac Death risk, and EAST high, an BHF funded clinical trial looking at stroke prevention in people with co-morbidities. Providing Trial Management expertise, the Trial Manager will also support other studies within the portfolio where necessary. The post holder must be able to use their own initiative, be an effective team player and excellent communicator.

Resources Managed

You will report directly to the EP Research Manager to support the successful conduct of the research portfolio ensuring adherence to ethical and regulatory approvals, sponsor SOPs, the principles of GCP and applicable EU Directives and UK legislation at the Glenfield as lead site and at participating sites. You will provide support to the EpRG and will act as the first point of contact for staff working on the project.

Main Duties and Responsibilities

- Once approvals are in place to undertake site initiation visits throughout the UK to commence recruitment at participating sites, providing site support in the form of trial-specific guidance notes and study specific training. Whilst recruitment is ongoing monitor site performance, ensure adherence to GCP and undertake quality checks of data 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 participating sites which may affect recruitment, protocol adherence or patient safety. Conduct problem solving/ quality assurance monitoring visits as required. Once site-based activities have ceased to close down sites.
- To facilitate trial oversight by the organisation of monthly management meetings, convene and manage Trial Steering and Data Monitoring Committees. Prepare general, study and finance progress reports for both oversight committees and funder.
- To support the EpRG PPI activities including attending public events, providing organisational support for meetings including payments and communications and social media outputs.
- To support the set-up of clinical trials including: the development of trial protocols, patient facing documents, case report forms and IRAS completion to obtain sponsor, HRA/MRA approvals.

Ensure trial processes are in place to demonstrate compliance with sponsor SOPs and where necessary create and implement study specific SOPs. Liaise with the Research and Enterprise Division (RED) for contract and finance set-up.

- To be a proactive contributing member of the multi-disciplinary team accountable to the EpRG lead and EP Research Manager, developing and running clinical trials. To be the key contact for specific trials and to coordinate and support the activities of the research group and collaborators. Organise and facilitate regular team meetings to ensure the progress of the projects, including minute-taking. Send out reminders to the EpRG and collaborators about upcoming deadlines and meetings.

Internal and External Relationships

Internal: Electrophysiology research team, including the Chief Investigator and Project Managers, BRC cardiovascular delivery team, senior investigators, academics, clinicians and staff.

External: Research portfolio study teams, Active personnel at participating sites, UK clinical trial regulatory bodies, UHL NHS Trust R&D Managers, Other NHS Trusts, Research Sponsors, project collaborators and Industry partners

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 EpRG trials 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 team members or the chief investigator.
- Coordinate and oversee study through effective communication with research staff in participating sites and the networks, collaborators, and other members of the trial team, representing the department in a professional manner.
- Manage the day-to-day running of the trials 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. Monitor the trial budget, advising the trial team

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*
- Sound knowledge of the principles of research governance and ICH-GCP*
- 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*
- Knowledge of HRA and MHRA application process and requirements*
- Proven project management and line management skills*

Desirable

- Experience of preparing publications and submitting grant applications.

Skills, Abilities and Competencies

Essential

- Ability to demonstrate behaviours that are in accordance with the University values of inclusive, inspiring and impactful
- Demonstratable experience of managing trials, systems and procedures*
- 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, as well as collaboratively as a team
- Must demonstrate a critical and intelligent attention to detail and high standards of accuracy*
- Ability to travel locally and nationally*

Desirable

- 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

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

UNIVERSITY OF LEICESTER

Job Summary

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 equity 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 equity, diversity and inclusion.