UNIVERSITY OF LEICESTER

Job Summary

Job Title: Vascular Trial Manager
Grade: 6
Salary: £33,002 to £37,694 per annum, pro rata if part-time
Department: Cardiovascular Sciences
Hours/Contract: Full-time, part-time (minimum 0.6FTE, 22.5 hours per week), or job share considered, fixed term contract until 12 months
Job Family: Management and Administration
Reference: 12289

Role Purpose

We are looking for a confident, proactive individual who can hit the ground running, is reflective in their approach, and committed to their ongoing development. Based within the Vascular Research team at the University of Leicester, the post-holder will support the trial management delivery and monitoring of the UK arm of the Metformin Aneurysm Trial (UKMAT), a large-scale international multicentre CTIMP (Clinical Trial of an Investigational Medicinal Product).

This is an exciting opportunity to support the UK delivery of a high-impact trial, working as part of a supportive and ambitious team. Reporting to the Senior Clinical Research Manager (under the BHF Chair of Vascular Surgery), the post-holder will be a key player in the trial management delivery of UKMAT working with The George Davies Vascular Research Manager and the Trial Monitor to support on-site monitoring visits at NHS sites across the UK, ensuring compliance with the Sponsor's Monitoring Plan, ICH-GCP, UK regulatory requirements, and the trial protocol, in collaboration with the international Sponsor and central medical monitor (Australia). The post-holder will also occasionally help to support other studies in the vascular portfolio, as and when needed, led by the BHF Chair of Vascular Surgery Professor Matt Bown and NIHR Professor Thanos Saratzis.

The role is ideal for someone who takes initiative, builds strong working relationships, and contributes positively to a learning-focused, team-based culture. You'll need excellent communication, organisational, and problem-solving skills, along with the ability to travel locally and nationally as and when needed, working flexibly and independently in a dynamic academic research environment working with lots of teams.

Main Duties and Responsibilities
Trial Management • 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 central/remote monitoring as required. Once site-based activities have ceased to close down sites. To support PPI activities including attending public events and disseminating communications and social media outputs. Also support site engagement and communications via newsletters. • To support setup of clinical trials including development and amendment of protocols, patient facing information, case report forms, and related documentation for HRA, MHRA, and REC submissions. Once approvals are in place to undertake site initiation visits throughout the UK

to commence recruitment at participating sites, provide site support in the form of trial-specific guidance notes and study-specific training.

- To facilitate trial oversight by the organisation of monthly management meetings, convene and manage Trial Steering and Data Monitoring Commitees. Prepare general, study, and finance progress reports for both oversight committees and funder and support meetings, including minute-taking.
- Ensuring trial processes are in place to demonstrate compliance with Sponsor SOPs and where necessary create and implement study specific SOPs. Liaise with Research and Enterprise Division (RED) for contract and finance. In the event of a statutory inspection, to assist with the preparation and conduct of the inspection. Support the review and reporting of pharmacovigilance reports; monitor IMP supply across UK sites, liaising with Sponsor and pharmacy teams to maintain continuity; and contribute to CAPA planning, inspection readiness, and the UK monitoring strategy as and when needed.

Monitoring and as and when needed (e.g. to cover illness, time-off, holidays, or reduced study management capacity), supporting national monitoring:

- Conduct planned and triggered monitoring visits at UK NHS sites and accurately document findings in line with the Sponsor's Monitoring Plan, ICH-GCP, protocol, SOPs and applicable legislation to verify site compliance with the trial protocol, other trial documentation, training, and regulatory expectations. Activities include Source Data Verification (SDV), verification of Informed Consent Forms, eligibility, pharmacy records, drug accountability, delegation logs, training logs, and other trial documentation to ensure version control, proper filing, and checking adherence to ALCOA+ principles, in addition to review of other operational elements (such as recruitment, retention, and data entry timelines). The monitor will be required to provide constructive feedback to sites, discuss and agree corrective actions, ensure timely follow-up of queries raised, reporting and resolution tracking; and ensure continuity of oversight across visits.
- Prepare and maintain trackers, issue logs, protocol deviation logs, and follow-up records to support structured oversight and inspection readiness. To write monitoring reports within timescales and follow up on unresolved issues identified during monitoring visits, maintaining accurate records of monitoring activity.
- Independently plan and coordinate on-site monitoring visits according to he monitoring plan, liaising with site staff (e.g. Principal Investigators, research nurses, pharmacy, laboratory teams) and the central medical monitor (when required). Track monitoring-related expenses (including travel arrangements) to support budget reviews with the Senior Clinical Research Manager.
- Conduct remote and central monitoring of UK sites where appropriate, including review of trial data in the Zelta database. Work in collaboration with the central monitoring teams to follow up and resolve data queries. To contribute to central monitoring oversight and risk-based reassessments of sites, escalating concerns and issues found during monitoring to the central medical monitor, sponsor, and trial management team, as appropriate.

Misc

- As and when necessary/needed to engage in continued professional development to remain current with legislation and best practice relating to clinical trials and trial monitoring.
- As and when necessary/needed to undertake additional, relevant duties as required by the

Senior Clinical Research Manager (under the BHF Chair of Vascular Surgery) to support research project delivery within the team.

Internal and External Relationships

Internal: Vascular research team, including Chief Investigators, Research Managers, BRC cardiovascular delivery team, senior investigators, academics, clinicians, and other staff (e.g. professional services).

External: International partners/collaborators, Trial oversight committees, Sponsor, regulatory authorities, funders, NHS Trusts, site staff, Research Delivery Networks, and commercial companies/industry.

Planning and Organising

- Take overall responsibility for trial management in compliance with regulatory guidelines, the monitoring plan, sponsor SOPs, working in liaison with the central medical monitor and the rest of the UKMAT trial management team. Maintain up-to-date knowledge of regulatory, ethical and governance requirements, as well as any changes to the protocol, and translate this to practical activities.
- Effective workload and project planning without reference to others (including travel and overnight stay arrangements). Set and ensure that quality assurance procedures are followed for all aspects 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 involvement of senior team members, the central medical monitor, Sponsor, and/or Chief Investigator.
- Coordinate and oversee trial monitoring through effective communication with research staff in participating sites, collaborators, the trial steering committee, and other members of the trial team, representing Leicester Vascular Research in a professional manner.
- Manage the day-to-day running of the monitoring programme supporting the running of the trials by establishing standardised procedures that ensure compliance with the protocol and regulatory standards, taking decisions on actions required. This requires a high level of organisation with exceptional attention to detail including high standards of accuracy and an ability to forward plan with prioritisation of tasks, adjusting priorities as needed, and workloads to ensure deadlines are met. Monitor the monitoring budget, advising the trial team.

Qualifications, Knowledge and Experience

Essential

- A degree or equivalent in a relevant biomedical science of associated subject OR associated subject experience with practical experience as a Trial Manager/Coordinator/Monitor in clinical trials research*
- Clear understanding and sound knowledge of research governance, ICH-GCP, and regulatory requirements for CTIMPs*

- Experience of working with data and interrogating clinical research databases (e.g. Zelta)*
- Sound knowledge of Quality Systems relating to clinical research*
- Proven project management skills*
- Previous experience within the NHS OR sound knowledge of running research within the NHS OR working with NHS staff*

Desirable

- Experience of working on international trials (e.g. Australia)
- Experience of multi-centre trials (i.e. setup, management, and/or monitoring).
- Experience of MHRA inspections
- Clinical research experience/knowledge of medical in the vascular field would be an advantage
- Evidence of monitoring course attendance
- Line management experience

Skills, Abilities and Competencies

Essential

- Able to demonstrate behaviours that are in accordance with the University values of being inclusive, inspiring, and impactful, and possess the ability to positively influence the way a team works together
- Self-motivated with ability to manage and prioritise own workload
- Excellent administrative, clerical, office management, and computing skills including advanced word processing, email, and spreadsheets.
- Effective communication, negotiation, presentation and inter-personal skills
- Demonstratable experience of managing/monitoring trials, systems and procedures*
- Able to identify and resolve problems by applying judgment and initiative*
- Able to deal with sensitive information in a confidential manner as well as offer proactive advice and guidance with tact and diplomacy *
- Able to understand, interpret, and critically analyse information to prepare reports*
- Must demonstrate a critical and intelligent attention to detail and high standards of accuracy*
- Willingness and ability to travel locally and nationally*

Desirable

- Working/responding independently and the ability to deal with unforeseen or challenging circumstances with the self-confidence and ability to cope under pressure

Criteria to be used in shortlisting candidates for interview

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Job Summary

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.

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 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.