



<b>Job Title:</b>	Vascular Trial Manager
<b>Grade:</b>	6
<b>Salary:</b>	£33,002 to £37,694 per annum
<b>Department:</b>	Cardiovascular Sciences
<b>Hours/Contract:</b>	Full-time, or job share considered, or part-time (minimum 0.6 FTE), contract available until 31 March 2027 with possibility of extension.
<b>Job Family:</b>	Management and Administration
<b>Reference:</b>	12943

## 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.

This is an exciting opportunity to support vascular studies, at various stages of setup and closedown working as part of a supportive and ambitious team within the Vascular Research team at the University of Leicester.

Reporting to the Senior Clinical Research Manager (under the NIHR Research Professor of Vascular Surgery and the BHF Chair of Vascular Surgery), the post-holder will be a key player in the trial management setup and delivery of IVL L6 – a small cohort registry study in the UK. This post will also provide exposure to international research as this will involve liaising with Swiss and Italian sites and is the perfect opportunity for an ambitious trial administrator/coordinator looking to get exposure to international research on a smaller scale, with the support of the Senior Clinical Research Manager and the Chief Investigator. It will also involve the active management of some other smaller studies within the portfolio, including those in closedown and as such will provide good exposure for the post-holder to the full trial/study lifecycle.

The post-holder will also occasionally help to support other studies in the vascular portfolio, as and when needed, led by the NIHR Research Professor, Professor Thanos Saratzis and the BHF Chair of Vascular Surgery Professor Matt Bown. This might involve development opportunities to support of the UKMAT trial (CTIMP) with aspects of trial management/monitoring with support of other Vascular Trial Monitors, Managers and The George Davies Vascular Research Manager.

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, and when needed, working flexibly and independently in a dynamic academic research environment working with lots of teams.





## Main Duties and Responsibilities

### Trial Management:

- To be a proactive contributing member of the multi-disciplinary team accountable to the Chief Investigator(s) and Senior Clinical Research 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, including preparation of agendas, minutes, and follow up of outstanding actions.
- 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 trial risk assessments and devise quality assurance plans in line with Sponsor processes. To undertake quality checks and assurance audits to maintain trial quality, highlighting any deviations for further relevant action, including any monitoring as and when needed.
- 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.
- 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.
- 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 management teams, funding bodies, regulatory authorities, ethics committees, Investigators, Trial Steering and





Data Monitoring Committees, funding bodies and external collaborators.

**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 and NIHR Research Professor 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. 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 Vascular research team 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 Senior Clinical Research Manager.





## 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\*
- 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\*
- Experience of working with data and interrogating clinical research databases (e.g. MACRO, REDCap)\*
- An understanding of Quality Systems relating to clinical research\*
- Proven project management \*
- 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
- 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
- Line management experience

## 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.

### 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.

### 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.

