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# Clinical Trial Manager (temporary role)

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| **Department/Division/Faculty:** | Surgery & Cancer |
| **Campus/Location:** | St Mary's Hospital / Stadium House |
| **Job Family/Level:** | Professional Services, Level 3b (Pay scale) |
| **Responsible to:** | Chief Investigator |
| **Key working Relationships (Internal):** | Chief Investigator; ICTU Operations Manager, Division of Surgery Management Team, Imperial Clinical Trial Unit (ICTU), Joint Research Office (JRO) and Regulatory Compliance Team, colleagues across the Faculty of Medicine, clinical staff at Imperial Healthcare NHS Trust. |
| **Key Working Relationships (External):** | NIHR (funder), collaborators (QMUL, LSHTM, Universities of Northumbria, Leicester, and Nottingham), contracted service providers, collaborating centres throughout the UK. |
| **Contract type:** | Full time and fixed term for 3 months (Temporary Position) |

## Purpose of the Post

This post will be based within the Department of Surgery and Cancer, both in the Imperial Vascular Unit at St Mary's Hospital and the UKCRC registered Imperial Clinical Trials Unit (ICTU).

The post holder will oversee a NIHR-funded clinical trial in vascular surgery and will be responsible for all aspects of trial management and monitoring, including close liaison with the Chief Investigator and PIs at other centres, management of the associated study and implementing/adapting established ICTU systems to ensure the trial is conducted to the highest scientific and regulatory standards. The trial is currently in its centre set-up and participant recruitment phase.

ICTU works to bring together academic and trial management expertise to deliver world class clinical trials of all phases. Trial designs range from early stage to large confirmatory studies, with a focus currently on a number of therapeutic areas including cancer, cardiovascular and metabolic diseases, respiratory disease, emergency medicine and critical care, HIV and infectious diseases and surgery.

## Key Responsibilities

*Trial Management*

- Be responsible for all coordination, administrative activities, and data management to ensure the efficient running of the allocated trial.
- Establish and maintain good communication between all key stakeholders e.g. study team, the Sponsor, the funder, collaborators, and staff at participating sites.
- Implement the principles of the International Conference on Harmonisation Good Clinical Practice (ICH-GCP) guidelines for clinical trials and ensure that all study personnel work according to them.
- Obtain/ assist with applications for initial approvals and ensure on-going adherence to the requirements of the regulatory bodies i.e. NHS Research & Development, Research Ethics Committee (REC) and Health Research Authority (HRA); and submit amendments as appropriate.
- Contribute to the development of all study documentation, under the guidance of other experienced Trial Managers / Operations Managers / Chief Investigator (CI) / Trial Management Group (TMG) including Study Protocol, Patient Information Sheet, Consent Form, GP letter and any other study materials as appropriate.
- Contribute to the development of the trial electronic database.
- Work together with other members of the group to ensure that the electronic CRF is provided in a timely way and works efficiently.
- Develop and implement comprehensive procedures for timely and clear reporting of trial status including progress and recruitment rates.
- Co-develop standard operating procedures (SOPs) for the coordination of the study.
- Manage the set-up of new sites.
- Ensure necessary reporting of adverse events, expedited SAE reporting and submission of Annual Reports.
- Coordinate and prepare trial endpoint adjudication packages and support the Endpoint Adjudication Committee.
- Coordinate and support the activities of the Trial Management Group, Steering and Data Monitoring Committee and other collaborative groups, including PPI.
- Provide cross-study cover for other members of the Unit as required.
- Assist in preparation of presentations and publications.
- Assist in the study risk analysis and preparation of the monitoring plan.
- Assist with the preparation and conduct of GCP inspections and internal audits.

*Trial Monitoring*

- Ensure that the study is conducted in compliance with protocol, overall clinical objectives, ICH GCP and the ICTU SOPs and are run according to agreed timelines.
- Train the staff from the research sites in the conduct of the study, documentation, record keeping and regulations.
- Maintain central records for the research sites including maintenance of the Trial Master Files (TMFs) as well as creation and distribution to sites of the Investigator Site Files (ISFs).
- Set up and attend regular meetings with study staff, with staff at the co-ordinating centres, and to facilitate communication between them.
- Assist with compliance with ICH-GCP and local regulations at all research sites.
- Conduct regular monitoring visits to participating sites in accordance with the study monitoring plans.
- Monitor recruitment / sample collection and assist with site payments, if appropriate.
- Perform Source Data Verification (SDV) of study data at participating sites to check original source. documents against what has been entered into the study database.
- Perform central monitoring of studies via the online study database.
- Identify and resolve queries in between monitoring visits.
- Check patient informed consent forms, ISFs and Serious Adverse Events (SAEs) for accuracy and

completeness on study visits.
- Perform Site Initiation Visits and study closeout visits as required.
- Write reports and follow up letters to sites following site visits and to monitor and record follow up of action points resulting from those visits.
- Raise any areas of concern identified at site visits with the Operations Manager and/or QA Manager as appropriate.
- Distribute and supervise all study documentation and equipment required for the purpose of the study.
- Arrange with study staff for the creation and maintenance of patient files and study documentation.
- Facilitate the correct completion of patient record forms, and to investigate missing forms.
- Maintain patient confidentiality at all times.
- Maintain a log of patient status in assigned sites.
- Liaise with the relevant laboratories as required.
- Offer administrative and research support to staff in the Vascular Science team and ICTU as required by the Chief Investigator, Operations Manager, and ICTU Directors, including support and guidance to less experienced monitors.

*Finance*

- Monitor trial finances, reviewing expenditure against budget and ensure adherence to terms of all relevant contracts in collaboration with the Operations Manager and ICTU Administrative team.
- Oversee payments made to investigators and assist with development of payment / tracking systems to ensure accountability.
- Monitor contractual arrangements (including the development of new contracts) with outside organisations as required.

*General*

- Undergo any training deemed to be necessary for the full execution of trial duties.
- Liaise with other Trial Managers to assist with the smooth running of the Vascular Science ICTU portfolio and to ensure support for other Trial Managers and associated staff as necessary.
- Represent the trials unit at meetings as required.
- Be familiar with the relevant clinical literature and keep up-to-date with literature relating to clinical research / trial methodology.
- Perform any other duties which may be required that are consistent with the nature and grade of the post as required by the Chief Investigator and/or the Operations Manager.
- Ensure familiarity with and adherence to all relevant ICTU and JRO SOPs.

*Other*

- To observe and comply with all College policies and regulations, including the key policies and procedures on Confidentiality, Conflict of Interest, Data Protection, Equal Opportunities, Financial Regulations, Health and Safety, Imperial Expectations (for new leaders, managers and supervisors), Information Technology, Private Engagements and Register of Interests, and Smoking.
- To undertake specific safety responsibilities relevant to individual roles, as set out on the College Website Health and Safety Structure and Responsibilities page (http://www3.imperial.ac.uk/safety/policies/organisationandarrangements)

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# Person Specification

| Requirements<br>Candidates/post holders will be expected to demonstrate the following: | Essential (E)/ Desirable (D) |
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| **Education** | |
| Bachelor's degree or equivalent in biomedical/scientific field | E |
| Postgraduate qualification or equivalent, which includes clinical trials methodology | D |
| **Experience** | |
| Proven clinical trial/project management experience gained in multi-centre, phase II and/or phase III, randomised trials | E |
| Comprehensive understanding and experience of clinical trial monitoring including source data verification | E |
| Evidence of preparing regulatory and ethics submissions, writing/amending protocols, patient information sheets, case report forms (CRF) /electronic CRF, and other relevant trial management documentation. | E |
| Experience of working in a research environment | E |
| Evidence of strong IT literacy (MS Office) | E |
| Experience of electronic database build requirements, data entry and data management processes using electronic CRFs | E |
| Previous experience/exposure to clinical practice | E |
| Experience of working within the NHS or academic clinical research setting | E |
| Proven experience in coordinating vascular trials | D |
| Evidence of a basic understanding of imaging data transfer procedures within clinical trials | D |
| Experience in preparing endpoint adjudication documentation and participating in Endpoint Adjudication Committee meetings. | D |
| Demonstrated success in the management of clinical trials budgets | D |
| **Knowledge** | |
| Working knowledge of the current EU Clinical Trials Directive, UK Clinical Trials regulations, Principles of GCP, Data Protection Act and Research Governance Framework legislation and proven ability to apply these to the coordination of clinical trials | E |
| **Skills & Abilities** | |
| Strong motivational skills | E |
| Evidence of ability to work independently as well as part of a team | E |
| Evidence of effective communication, negotiation, presentation and inter-personal skills | E |
| Evidence of ability to work with critical attention to detail and high levels of accuracy | E |
| Proven excellent organisational and time management skills to effectively handle conflicting priorities and ensure tight deadlines are met | E |

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| Willingness to travel within the UK | E |
| Willingness to work flexibly outside of office hours on occasion e.g., for travelling to and from sites | E |
| Willingness to undergo any training deemed to be necessary for the full execution of trial duties | E |

## Further Information

Please note that job descriptions cannot be exhaustive, and the post-holder may be required to undertake other duties, which are broadly in line with the above key responsibilities.

Our values are at the root of everything we do and everyone in our community is expected to demonstrate Imperial:

- Respect
- Collaboration
- Excellence
- Integrity
- Innovation

Employees are also required to comply with all Imperial policies and regulations.

We are committed to equality of opportunity, to eliminating discrimination and to creating an inclusive working environment for all. We encourage candidates to apply irrespective of age, disability, marriage or civil partnership status, pregnancy or maternity, race, religion and belief, gender reassignment, sex, or sexual orientation. You can read more about our commitment on our webpages.

**[Aug 2026]**