IMPERIAL

Clinical Trials Manager

Department/Division/Faculty:	Surgery and Cancer, Faculty of Medicine
Campus/Location:	Hammersmith, Charing Cross and South Kensington
Job Family/Level:	Professional Services Level 3b (Salary scales)
Responsible to:	Professor Hashim Ahmed, ECMC Co-Lead – (Surgery & Cancer
Line management for:	None
Key working Relationships (Internal):	Early Phase Trials Operations Manager, Chief Investigators; Surgery studies delivery team, Cancer & Haematology delivery teams, Joint Research Office (JRO) and Regulatory Compliance Team, colleagues across the Faculty of Medicine, clinical staff at Imperial
Key Working Relationships (External):	Funder, contracted service providers, collaborating centres, NIHR, Statisticians, database teams
Contract type:	Fixed-term until 30th March 2028

Purpose of the Post

The post holder will oversee the coordination and follow up of a range of academically funded multi-centred randomised clinical trials within the Surgery portfolio. You will be responsible for all aspects of trial management, including close liaison with the Chief Investigator and PIs at other centres, management of the associated study staff and implementing / adapting established Imperial College London/NHS Trust systems and processes to ensure the trial is developed and conducted to the highest scientific and regulatory standards. The post will include monitoring the quality of data collected from the electronic CRF and from patient records.
This post will be based within the Department of Surgery and Cancer in the Surgery section of the Imperial ECMC. The day to day line management will be provided by the ECMC Surgery Lead with regular collaboration with the Imperial CTU, ICHT Research Operations Manager and Divisional Research Manager. The research methods employed within the group include clinical projects, including set up

and running of early phase surgery and interventional cancer trials, molecular and cellular biology, and biobanking.
The post holder will work across both Imperial College London and Imperial College Healthcare NHS

Trust and other affiliated NHS Trusts, delivering clinical trials of early phases.
Activities encompass all aspects of the conduct of clinical trials from initial design through to successful delivery and dissemination of results. ECMC provides expertise in trial methodology and management across several key disease areas including surgical and interventional cancer studies and works closely with the Joint Research Compliance Office and RGIT of Imperial College London and NHS Trust to ensure that the regulatory, legal and quality control aspects of trials are met.
The expansion of the Surgery and Interventional theme within ECMC will allow exciting opportunities to develop and support the portfolio of clinical trials, whilst maintaining a reputation for conducting high quality work.

Key Responsibilities

Trial Management
▪ Oversee trial coordination, data management and administrative activities to ensure the smooth running and progress of the trial.
▪ Work closely with CI, statisticians, academic collaborators, vendors and funding partners to ensure good communication between all parties.
▪ Obtaining appropriate ethical and regulatory requirements and ensuring ongoing compliance
▪ Ensure the safe conduct of the trial with adherence to necessary pharmacovigilance e.g. reporting of adverse events, expedited safety reporting and submission of Annual Safety reports.
▪ Oversee the efficient supply of investigational devices to trial centres.
▪ Travel to national sites for site initiation/set up visits and monitoring.
▪ Develop and implement comprehensive procedures for timely and clear reporting of trial status including progress and recruitment rates.
▪ Act as a first point of contact for all issues relating to the creation and working of the electronic data capture system including the randomisation service.
▪ Work together with other members of the group to ensure that the electronic CRF is provided in a timely way and works efficiently.
▪ Manage timely and efficient procedures for collection, entry and monitoring of study data.
▪ Create Monitoring Plan and other essential trial documentation.
▪ Create and maintain all study files, including the trial master file (TMF) and have oversight of site files ensuring all essential documents are filed correctly and kept up to date.

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▪ Conduct monitoring of the studies at the study sites in accordance with ICH guidelines on clinical trial monitoring, local regulatory requirements and the study monitoring plan.
▪ Write reports and follow up letters to sites following site visits and monitor and record follow up of action points resulting from those visits.
▪ 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 remote monitoring of studies via the online study database to identify and resolve queries in between monitoring visits.
▪ Coordinate and support the activities of the Trial Management Group, Steering Committee, Data Monitoring Committee and other collaborative groups, including PPI.
▪ Assist in the recruitment and retention for the trial by preparing newsletters and posters etc.
▪ Promote the dissemination of trial results by making presentations at local, national and international meetings as required.
▪ Contribute to the writing of scientific papers as required.
▪ Review and continually refine trial systems and processes to ensure efficiency, effectiveness and standardisation in liaison with ECMC co-leads and Operations Manager.
▪ Completion of all annual progress reports to ethics, the Sponsor and Funder.

Finance
▪ Monitor trial grant, reviewing expenditure against budget and ensuring adherence to terms of all relevant contracts, in collaboration with the Departmental Administrator and Imperial Administrators.
▪ 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 Trials Managers to assist with the smooth running of the ECMC and to ensure support for other Trial Managers and associated staff as necessary.
▪ Represent the trials unit at meetings as required.
▪ Assist with the preparation and conduct for any future GCP Inspection.
▪ Be familiar with the relevant clinical literature and keep up-to-date with literature relating to clinical research / trial methodology.

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▪ 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 ECMC trials 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)

Person Specification

Requirements Candidates/post holders will be expected to demonstrate the following:	**Essential (E)/ Desirable (D)**
Education	
Bachelor's degree or equivalent E	E
Postgraduate qualification or equivalent, which includes clinical trials methodology	D
Experience	
Previous clinical trial/project management experience	E
Evidence of strong IT literacy (MS Office)	E
Experience of managing publicly funded applications	D
Evidence of working in surgery and cancer trials	E
Evidence of using an electronic CRF	D
Evidence of preparing regulatory and ethics submissions, writing/amending protocols, PIS, CRFs and other relevant trial management documentation	D
Demonstrated success in the management of clinical trials budgets	D
Working knowledge of the current EU Clinical Trials Directive, UK Clinical Trials regulations, Principles of GCP, Data Protection Act (GDPR) 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

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.

November 2026