

IMPERIAL

Clinical Trial Manager

Department/Division/Faculty:	Division of Cancer/ Department of Surgery and Cancer
Campus/Location:	South Kensington/ Roderic Hill Building/ Hybrid Working
Job Family/Level:	Clinical Trial Manager Level 3b; SP 28-34 (Salary Pay Scale)
Responsible to:	Cancer Clinical Trials Operations Manager / Deputy Cancer Clinical Trials Operations Manager
Line management for:	N/A
Key working Relationships (Internal):	Cancer Clinical Trials Operations Manager / Deputy Cancer Clinical Trials Operations Manager, Chief Investigator (CI), Clinical Trial Coordinators, Clinical Trial and Data Administrator, Imperial Clinical Trials Unit (ICTU) where relevant, Research Governance and Integrity Team (RGIT)
Key Working Relationships (External):	Participating research sites, co-investigators, oversight committees, collaborating funders, pharmaceutical companies, research and regulatory authorities
Contract type:	Full time and Fixed Term

Purpose of the Post

You will undertake the day-to-day management of one or more clinical trials currently active in the Imperial Clinical Trials Unit-Cancer (ICTU-Ca) portfolio. You will be responsible for all aspects of trial coordination to ensure that each study is conducted to the highest scientific and regulatory standards, to time and within budget.

Key Responsibilities

Trial Coordination

- Be responsible for all coordination and administrative activities to ensure the efficient running of the allocated trial/s.
- Establish and maintain good communication between all key stakeholders e.g. study team, ICTU where relevant, RGIT, funders, pharmaceutical collaborators, academic 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, Health Research Authority (HRA), Medicines and Healthcare products Regulatory Agency (MHRA) and Research Ethics Committee (REC) and submit amendments as appropriate.
- Maintain the Trial Master File (TMF).
- Contribute to the development of all study documentation under the guidance of the Cancer Clinical Trials Operations Manager / Deputy Cancer Clinical Trials Operations Manager / CI / Trial Management Group (TMG) including Study Protocol, Participant Information Sheet, Consent Form, GP letter and any other study materials.
- Co-develop specific standard operating procedures (SOPs) for the initiation and coordination of the study.
- Set up new sites and conduct site initiation visits (SIVs) as required.
- If applicable, liaise with pharmacies and ensure timely supply of investigational medicinal product (IMP) to sites.
- Ensure necessary pharmacovigilance by reporting adverse events including expedited serious adverse event (SAE) and suspected unexpected serious adverse reaction (SUSAR) reporting and submission of Development Safety Update Reports (DSURs).
- Convene meetings of the TMG, Trial Steering Committee (TSC) and Independent Data Monitoring Committee (IDMC) and provide associated documentation.
- Undertake on-site and central monitoring according to the monitoring plan and in line with the risk assessment, data management activities (see below) etc.
- Supervisory responsibility for and support of the Clinical Trial and Data Administrator e.g. general administrative activities, translational research activities (see below) etc.
- Monitoring of trial finances under guidance from the Cancer Clinical Trials Operations Manager / Deputy Cancer Clinical Trials Operations Manager.
- Manage processes for making payments to sites if appropriate.
- Assist in the preparation of reports/updates to study funders and any other bodies as required.
- Participate in the team randomisation/enrolment and pharmacovigilance service provided for all studies.
- Provide cross-study cover for other members of the team as required.
- Assist in preparation of presentations, abstracts and publications.

Translational Research

- If applicable, write, maintain and adhere to specific SOPs for the collection, processing, storage and transportation and storage of participant biological samples to ensure compliance with regulatory requirements.
- If applicable, maintain an up-to-date tracking system for biological samples.
- If applicable, facilitate the distribution of biological samples for analysis and collation of results.

Data Management

- Together with the study statistician/s, database developer(s) and other team members, to develop and maintain the electronic Case Report Forms (eCRF).
- Manage timely and efficient procedures for collection, entry and verification of all patient data, raising queries for missing or incomplete data as appropriate.
- Ensure quality and completeness of data using appropriate quality control measures.
- Assist in the production of written reports as required.
- Submit accrual figures to relevant groups.

General

- 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 Cancer Clinical Trials Operations Manager, Deputy Cancer Clinical Trials Operations Manager or CI.

Other Duties:

- To undertake appropriate administration tasks
- [For members of staff who have responsibility for collecting, inputting and maintaining data]
To be responsible for ensuring that data is accurate, up-to-date and complete.
- To attend relevant meetings
- To undertake any necessary training and/or development

Any other duties commensurate with the grade of the post as directed by line manager / supervisor
Where Imperial or funder conditions necessitate, you will be required to complete timesheets for your work on projects in a timely manner.

Person Specification

Requirements

Candidates/post holders will be expected to demonstrate the following:

**Essential (E)/
Desirable (D)**

Education

First degree or equivalent experience in a related field	(E)
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Knowledge

Proven clinical trial coordination experience in IMP trials	(E)
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Experience of on-site monitoring, including source data verification	(D)
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Excellent working knowledge of relevant regulations, legislation and guidance	(E)
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and a proven ability to apply these to the coordination of a clinical trial	
Evidence of preparing regulatory and ethics submissions and amending	(E)

protocols, participant information sheets and other core trial management documentation	
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Experience of data management processes including Electronic Data Capture	(D)
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(ED) software	
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Experience of working on studies with a sample collection component	(D)
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Skills & Abilities

Evidence of effective communication, both orally and with the written word	(E)
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Proven ability to organise and prioritise workload to meet deadlines	(E)
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Proven ability to work independently as well as part of a team	(E)
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Proven ability to work accurately and methodically with a meticulous attention to detail	(E)
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Creative approach to problem solving	(E)
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IT literacy including the use of Microsoft Office	(E)
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Personal Attributes

Willingness to work as part of a team and to be open-minded and co-operative	(E)
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Flexible attitude towards work	(E)
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Discipline and regard for confidentiality and security at all times	(E)
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Willingness to work out of normal working hours (including weekends) if the requirements of the project demand	(E)
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Willingness to undertake any necessary training for the role	(E)
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Willingness to travel both within the United Kingdom and abroad to conduct research and attend conferences.	(E)
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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](#).

Imperial is a proud signatory to the San-Francisco Declaration on Research Assessment (DORA), which means that in hiring and promotion decisions, we evaluate applicants on the quality of their work, not the journal impact factor where it is published. For more information, see <https://www.imperial.ac.uk/research-and-innovation/about-imperial-research/research-evaluation/>

Imperial believes that the use of animals in research is vital to improve human and animal health and welfare. Animals may only be used in research programmes which are ultimately aimed towards finding new treatments and making scientific and medical advances, and where there are no satisfactory or reasonably practical alternatives to their use. Imperial is committed to ensuring that, in cases where this research is deemed essential, all animals in our care are treated with full respect, and that all staff involved with this work show due consideration at every level. [Find out more about animal research at Imperial](#).

September 2026