ICR The Institute of Cancer Research

Clinical Trial Manager
Candidate Information

16/04/2025

The Institute of Cancer Research

About our organisation

The ICR is one of the world's most influential cancer research institutes with an outstanding record of achievement dating back more than 100 years. The scientists at the ICR have contributed to identifying several cancer genes, discovered multiple practice changing cancer drugs and have developed precision therapies. Together with our hospital partner The Royal Marsden (RM), we are rated in the top four centres for cancer research and treatment worldwide.

The ICR was ranked first in the UK for its research in biological sciences in a combined assessment of research quality, impact and environment; and overall, second in the UK among all higher Education institutions in REF 2021 analysis.

As an academic institute, ICR is a college of the University of London and has a charitable status. The institute operates with funding support from grants, partner organisations, charities, donors, industry partners and the general public. The ICR has more than 1,000 staff, researchers and students across three sites – in Chelsea and Sutton.

Drug Development Unit / Clinical Studies

The Drug Development Unit, led by Professor Johann de Bono aims to seamlessly integrate preclinical drug discovery, proof-of-principle phase I trials and tumour-specific evaluation of novel agents. It is a conduit for the two-way communication between laboratory and clinical teams that is so essential for successful modern drug development. The unit conducts first-in-man phase I trials involving a range of targets, including growth factor or intracellular signalling, angiogenesis, apoptosis, epigenetics and DNA repair. All trials are underpinned by extensive analysis of biomarkers, both predictive and pharmacodynamics. The DDU includes The Oak Foundation Drug Development Centre (Oak Ward) housed within The Royal Marsden at the Sutton site and

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specifically designed for phase I clinical trials. Opened in February 2005, the centre provides 10 inpatient beds, five treatment chairs and two outpatient suites, and allows researchers to enter almost 300 patients onto phase I trials each year. This makes the unit one of the largest of its kind in the world.

The DDU also has a portfolio of investigator-initiated phase I trials of novel targeted agents and combinations of these, working with the Experimental Cancer Medicine Centre network across the UK and with other Phase I units internationally. These studies are centrally managed by a dedicated team within the DDU that performs those functions associated with sponsoring early phase trials including project management, monitoring, pharmacovigilance, database development and central data review. The successful applicant will be will be responsible for managing allocated Phase I clinical trials to agreed timelines and budget, ensuring compliance with GCP and the UK Clinical Trials legislation.

Our mission is to make the discoveries that defeat cancer.

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Our values

The ICR has a highly skilled and committed workforce, with a wide variety of roles, each requiring different skills. But whether you work as a researcher, or work as part of our corporate team, your work and behaviour is underpinned by these six values. They are what bring us together as one team - as 'One ICR'.

Pursuing excellence

We aspire to excellence in everything we do, and aim to be leaders in our field.

Acting with Integrity

We promote an open and honest environment that gives credit and acknowledges mistakes, so that our actions stand up to scrutiny.

Valuing all our people

We value the contribution of all our people, help them reach their full potential, and treat everyone with kindness and respect.

Working together

We collaborate with colleagues and partners to bring together different skills, resources and perspectives.

Leading innovation

We do things differently in ways that no one else has done before, and share the expertise and learning we gain.

Making a difference

We all play our part, doing a little bit more, a little bit better, to help improve the lives of people with cancer.

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Job description

Department / division:	Drug Development Unit / Clinical Studies
Pay grade / staff group:	Scientific Professional 5 / Research Management 2
Hours / duration:	Full time (35 hours per week), Monday to Friday. Fixed term contract for 12 months in the first instance.
Reports to:	Clinical Trial Programme Manager
Main purpose of the job:	The Clinical Trial Manager will be responsible for the full poject management of allocated trials from initial feasibility to final report and site closedown. The post-holder will liaise effectively with other key members of the study teams including the Chief Investigator, data managers, trial monitors, statisticians investigator site clinicians, site coordinators and research nurses, to ensure clinical studies meet the requirements of all legal and regulatory obligations and the Department of Health's Research Governance Framework.

Duties and responsibilities:

Trial initiation and Set Up

Develop trial related documents including the protocol, informed consent forms, pharmacy manual, lab manuals etc. Liaise with relevant members of the Trial Management Group (TMG) including the DDU Chief Investigators, Collaborators and ICR-CTSU methodological lead.
Develop a project plan as appropriate for the project (Roles and Responsibilities, Communication Plan, Risk Analysis, etc).
Prepare and finalise all essential study documentation for submission to Institutional Review (CCR), Research Ethics Committees (REC), Health Research Authority (HRA) and Regulatory Authorities (MHRA).
Ensure the required approvals and agreements are in place before the trial opens to recruitment.
Liaise with CRAs to plan and perform site initiation visits via teleconference or face-to-face ensuring sites have all applicable documentation in place and that principal investigators and site staff understand the protocol and their responsibilities within the trial.
Support CTPM with coordinating sub-contracted activities, designing process plan and oversight of assigned clinical trials.

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Ensure appropriate contractual arrangements are put in place to supply investigational medicinal products to investigational sites in accordance with Good Manufacturing Practice.

Trial management

Manage study timelines and all project deliverables for allocated studies, ensuring every trial is completed within allocated budgets, agreed timelines and are conducted to the highest standards of Good Clinical Practice.
Monitor recruitment rates against targets to identify problems and work with sites to implement any corrective actions plans.
Liaise closely with the CI, ICR-CTSU Statistician, CTPM, Statistician and other key members of the TMG to ensure on-going clinical, scientific and operational oversight.
Chair and lead internal trial team meetings.
Act as the principal point of contact for funder(s), pharmaceutical partners, regulatory authorities and the trial oversight committees.
Coordinate any trial-related biological sample collections and liaise closely with central laboratory teams.
Liaise with the Clinical Research Associate to ensure that a monitoring risk assessment is prepared and reviewed regularly and that monitoring is conducted in line with the latest version of the monitoring plan. Oversee and input content of Site Initiation Visit.
Update trial documentation as necessary e.g. protocols, trial guidance notes, case report forms (CRFs) and patient information sheets.
Prepare and submit amendments to the REC approval/CTA under the guidance of the CTPM, and in collaboration with relevant members of the TMG.
Draft regular progress and safety reports throughout the study as necessary e.g. to funding bodies, TMG, Trial Steering Committee, REC, MHRA.
Contribute to the preparation of abstracts, posters and manuscripts.
Prepare data for interim and/or full analysis in collaboration with the trial statistician, draft study reports including the final clinical study report.
Liaise with the statistician, data analyst and CRA to ensure data required for trial oversight committees is subject to the required quality control procedures as set out in the trial oversight committee charter.
Manage drug supply arrangements and oversee drug usage and re-supply at investigational sites.
Oversee sample tracking & reconciliation (sample management)

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Maintain quality control procedures for all aspects of trial conduct to ensure compliance with the principles of Good Clinical Practice, research governance standards and all applicable legislation (e.g. The Medicines for Human Use (Clinical Trials) Regulations, General Data Protection Regulation, Good Clinical Laboratory Practice, Human Tissue Act/Human Tissue Bill (Scotland)).
Maintain the Trial Master File to ensure a clear audit trail of trial activities is retained.
Facilitate any audit, inspection or progress visit processes required by regulatory bodies, or sponsor(s).

Trial Promotions and Communications

Liaise with participating sites and potential collaborators to promote trial recruitment.
Draft and circulate regular newsletters and essential communications across all parties.
Plan, organise and give presentations at meetings of investigators/research nurses/trial coordinators as appropriate.
Promote the trial at national scientific meetings developing presentation materials (slides/posters/flyers) as required.

Biological sample management

Develop procedures for biological sample management (collection, tracking and shipment) in collaboration with the central laboratory.
Coordinate the movement of pharmacokinetic and pharmacodynamic samples and the resulting data.
Develop procedures for biological sample reconciliation in liaison with the CRAs and central laboratory team, under the guidance of the Clinical Trial Operations Officer.

General duties

Attend and contribute to DDU's monthly research meetings, IIT team meetings and Trial Manager meetings.
Assist with the review and preparation of SOP's and guidance where necessary.
Assist with the set up of the new eTMF/CTMS system
All staff must ensure that they familiarise themselves with and adhere to any ICR policies that are relevant to their work and that all personal and sensitive personal data is treated with the utmost confidentiality and in line with the General Data Protection Regulations

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Person specification

Education and Knowledge

A medical, life science, nursing or pharmacy equivalent degree. Significant prior experience of working in a clinical trial environment combined with a non-science degree is also acceptable.	Essential
Knowledge of GCP (EU Directive 2001/20/EC and GCP Directive 2005/28/EC)	Essential
Knowledge of the specific requirements of Phase I oncology studies	Essential

Skills

Self-motivated and able to work independently, with excellent attention to detail	Essential
Proven ability to develop effective working relationships with staff at all levels	Essential
Good logistical and planning skills, ability to prioritise effectively	Essential
Excellent verbal and written communication skills	Essential
Good IT skills, proficient with the use of MS Office applications	Essential

Experience

Experience of working in accordance with ICH-GCP regulatory standards for the conduct of clinical trials and UK Research Governance.	Essential
A PhD in a relevant discipline or prior experience in or assistance with the planning, coordination and conduct of clinical trials at sponsor-level is essential.	Essential
Experience of monitoring or managing Phase I oncology trials	Desirable

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Benefits

We offer a fantastic working environment, great opportunities for career development and the chance to make a real difference to defeat cancer. We aim to recruit and develop the best – the most outstanding scientists and clinicians, and the most talented professional and administrative staff.

The annual leave entitlement for full time employees is 30 days per annum on joining.

Staff membership to the Universities Superannuation Scheme (USS) is available. The USS is a defined benefit scheme and provides a highly competitive pension scheme with robust benefits. The rate of contributions is determined by USS and details of the costs and benefits of this scheme can be found on their website. If staff are transferring from the NHS, they can opt to remain members of the NHS Pension Scheme.

We offer a range of family friendly benefits such as flexible working, a parents' group, and a maternity mentoring scheme. Other great benefits include interest free loans for discounted season tickets for travel and bicycle purchases, access to the NHS discounts website, a free and confidential Employee Assistance Programme which offers a range of well-being, financial and legal advice services, two staff restaurants, and access to a gym and sporting facilities at our Sutton site.

Further information

You may contact ddu.iit@icr.ac.uk for further information.

This job description is a reflection of the current position and is subject to review and alteration in detail and emphasis in the light of future changes or development.