Senior Clinical Trial Manager



Candidate Information

February 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

The Drug Development, within the Institute of Cancer Research is one of the leading Phase I Clinical Trials Units in the world. The Unit, led by Professor Johann de Bono and Professor Udai Banerji, delivering both academic and industry sponsored first in human and early phase Oncology clinical trials. The Unit comprises of ~140 staff members including Clinicians, Research Nurses, Scientists and Administrative support staff. We run ~50-60 clinical trials at any given time and care for ~800 patients per year.

The main aim of the Unit is to fast track the development of anti-cancer drugs, designed and synthesised in ICR or developed by CRUK or developed by industry collaborators, to maximise their potential towards the care of cancer patients. The Unit was involved in development of several practice changing cancer drugs, including Abiraterone and Olaparib. The Unit operates as a conduit, between laboratory research and clinical research that is fundamental to the modern drug development process.

Our mission  
is to make the discoveries that defeat cancer.

The Unit is one of the Experimental Cancer Medicine Centres in the UK, CRUK convergence science centre and Early Phase Drug Development Theme within NIHR Biomedical Research Centre. Unit has multiple academic and industry collaboration programmes both nationally and internationally, working together to serve out patients as quickly as possible.

The Investigator Initiated Trials (IIT) Team, a dedicated academic trials management team within The Drug Develop Unit, performs functions associated with sponsoring early phase trials including trial initiation, trial development, project management, monitoring, pharmacovigilance, database development, safety review and trials reporting. This team 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 successful applicant will be responsible for managing allocated Phase I clinical trials in DDU-IIT team at senior project management level and support smooth conduct of clinical trials across all trial sites.

**Further information is available at:**

**ICR**

[www.icr.ac.uk](http://www.icr.ac.uk/) | **Twitter** [@ICRnews](https://twitter.com/ICRnews) | **Facebook** [www.facebook.com/theinstituteofcancerresearch](http://www.facebook.com/theinstituteofcancerresearch)

**ICR-CTSU**

<https://www.icr.ac.uk/our-research/centres-and-collaborations/centres-at-the-icr/clinical-trials-and-statistics-unit>

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# Our values

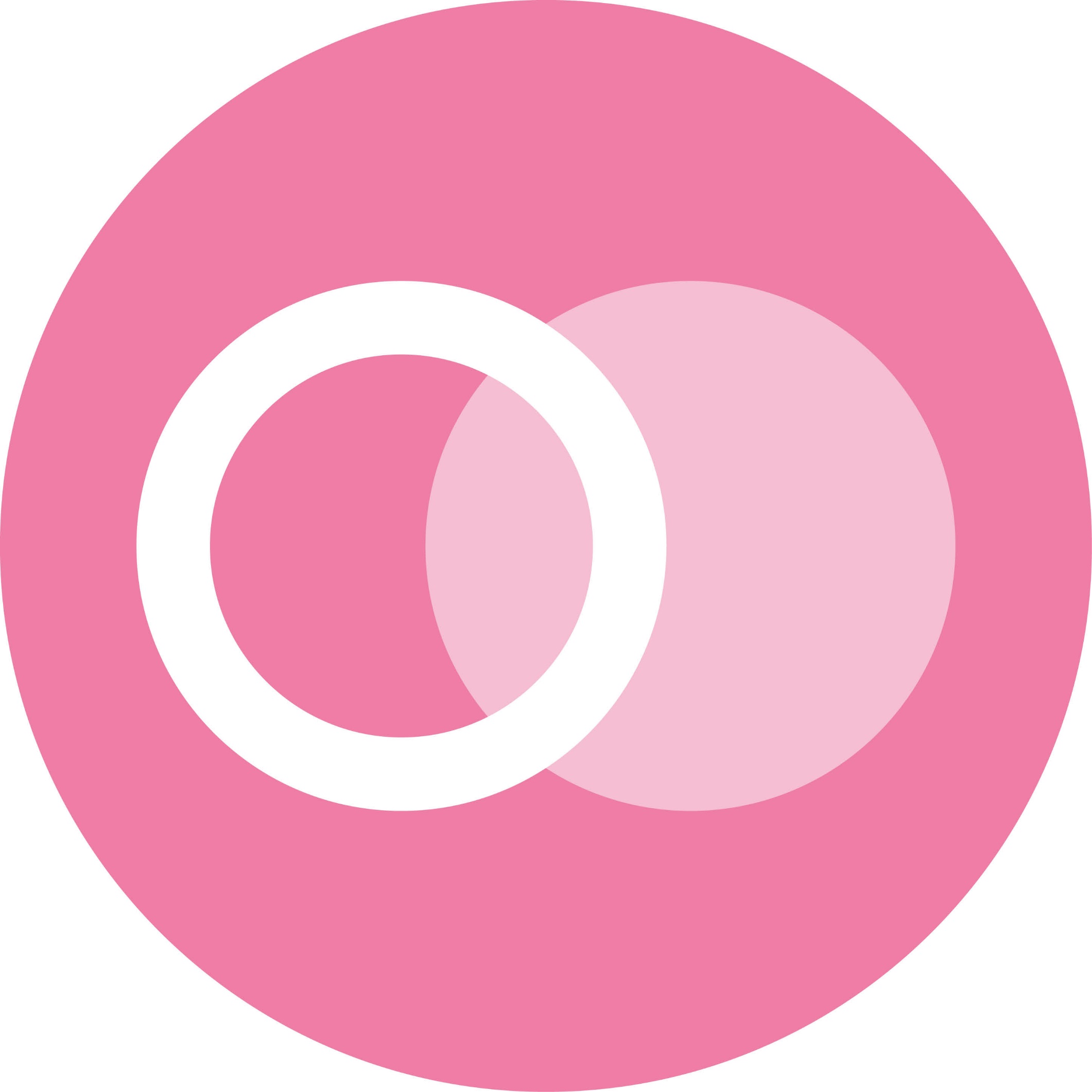
The ICR has a highly skilled and committed workforce, with a wide variety of roles, each requiring different skills. But whether you work as a researcher, or work as part of our corporate team, your work and behaviour is underpinned by these six values. They are what bring us together as one team - as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

## Pursuing excellence

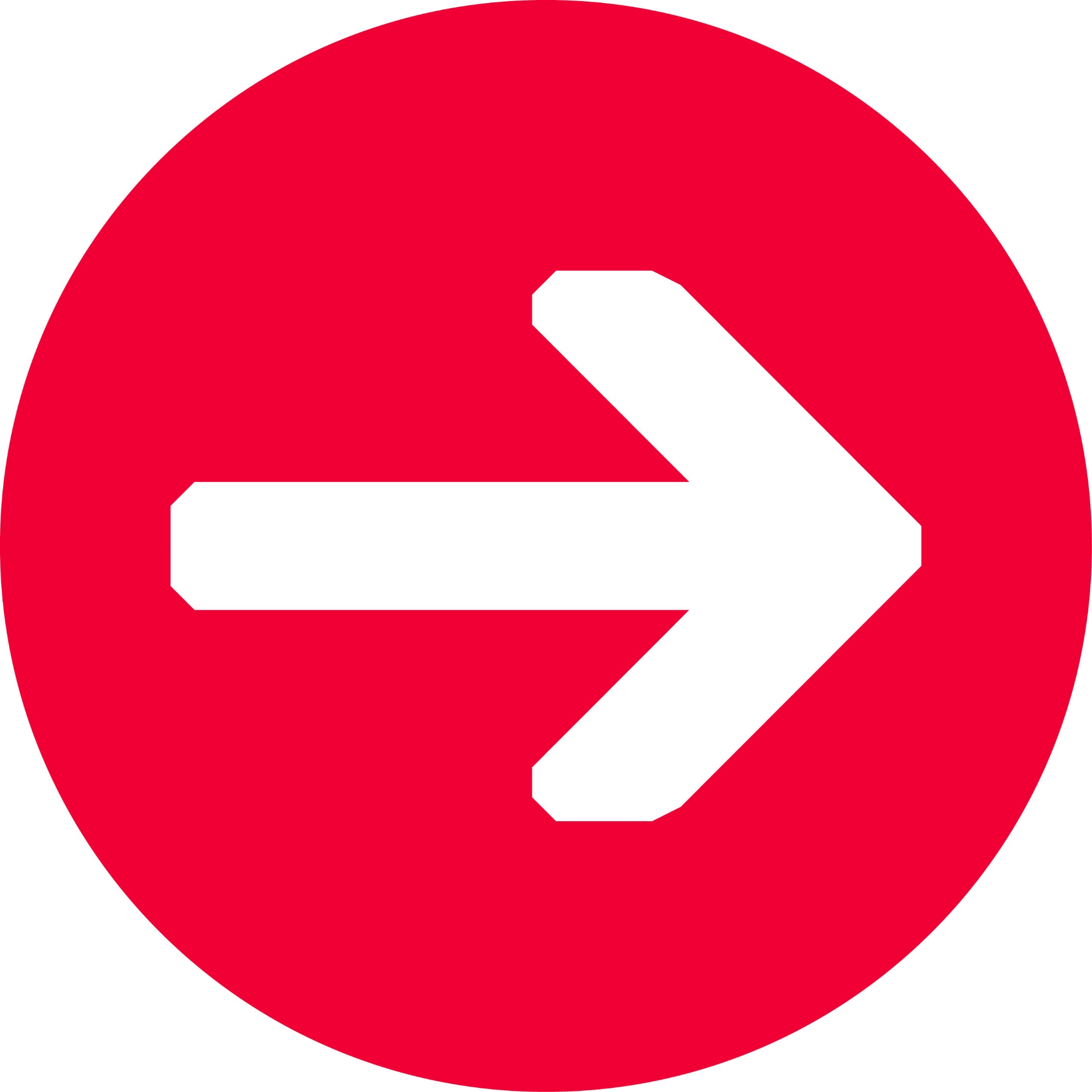












We aspire to excellence in everything we do and aim to be leaders in our field.

## 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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| **Department / division:**  Job description | Division of Clinical Studies |
| **Pay grade / staff group:** | Scientific Professional 4 / Research Management 3 |
| **Hours / duration:** | Full time (35 hours per week), Monday to Friday. Fixed term contract for 1 year. |
| **Reports to:** | Clinical Trial Programme Manager |
| **Accountable to:** | Head of IIT and Deputy Head of IIT |
| **Line Management:** | Junior staff in Research Management 1 and 2 grades |
| **Main purpose of the job:** | The post holder will be responsible for the day-to-day management of the trial(s) through initial feasibility, set-up, recruitment and reporting and the co-ordination of data management and biological sample management activities.  Post holder will proactively work with Clinical Trials Programme Managers (CTPM), Clinical Trial Managers, Statisticians, Clinical Research Associates, Clinical Data Analysts and Administrators and will liaise effectively with Chief Investigators and External collaborators to ensure smooth set up of trials and trial amendments.  Post holder will ensure clinical studies meet the requirements of all legal and regulatory obligations and the Department of Health’s Research Governance Framework and Institutional requirements.  Post holder will work under the supervision of a CTPM and assist CTPMs for over-all oversight for trials where required.  Post holder will be responsible for line management, training and mentoring of junior staff members and support their professional development.  Post holder will contribute and provide input to CTPM towards resource and workload management within the teams. |

Duties and responsibilities:

Trial initiation and Set Up

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| 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 the CRA 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 subcontracted activities, designing process plan and oversight of assigned clinical trials. |
| Ensure appropriate contractual arrangements are put in place to supply investigational medicinal products to investigational sites in accordance with Good Manufacturing Practice. |

Trial management

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| 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. |
| Organise and attend meetings of the trial oversight committees, preparing the agenda and meeting papers, and taking minutes as required. |
| 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. |
| Assist CTPMs with Trial Budget preparation and contribute to invoice management |
| 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

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| 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

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| 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 CRA’s and central laboratory team, under the guidance of the Clinical Trial Operations Officer. |

Senior Trial Manager Responsibilities

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| Take initiative and lead on trial set up activities, ensuring all aspects of trial set up are appropriately addressed. |
| Support and mentor less experienced Trial Managers on specific trials through teaching and training |
| Assist CTPM in resource planning and workload management |
| Provide back-up cover for CTPM where appropriate and with appropriate tasks. |
| Lead by example and contribute towards IIT team’s business planning |

Staff Management

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| Undertake all aspects of staff management, including recruitment, induction, training, performance management and appraisals. |
| Prioritise and allocate workloads within the trial team to ensure the trial is supported effectively and efficiently. Step in where appropriate and support staff to manage their workload. |
| Work alongside senior staff members to maintain good morale within IIT team. |

General duties

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| Attend and contribute to DDU’s monthly research meetings, departmental and IIT team meetings and Trial Manager meetings. |
| Support and participate in departmental working groups. |
| 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 |

In general, DDU-IIT staff work from 9 am to 5 pm with a one-hour lunch break. However, the post holder may be required to work outside these hours to meet deadlines and to attend on-site monitoring visits. It may also be necessary for the post holder to be available for occasional evening meetings and for meetings and monitoring visits to include overnight stops.

This role would usually be office based with some flexible working options are considered.

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In addition, there will be other duties consistent with the nature and grade of the post.

# Education and Knowledge

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| First degree or equivalent level qualification in biological science, social science or other relevant subject (including nursing and health care disciplines). | Essential |
| A sound understanding of the principles of Good Clinical Practice, Data Protection, the EU Clinical Trials Directive and research governance. | Essential |
| A good understanding of medical terminology and clinical trial design | Essential |
| Excellent knowledge of PC based Windows and Microsoft Office software. | Essential |
| An understanding of cancer and its treatment modalities | Desirable |
| Expert knowledge of trial management systems and processes | Essential |

Skills

Person specification

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| Ability to work accurately, with a strong attention to detail | Essential |
| Excellent organisational and time management skills | Essential |
| Excellent oral and written communication skills | Essential |
| Ability to maintain adherence to written procedure and clinical and regulatory standards applicable to DDU-IIT clinical trials | Essential |
| Excellent interpersonal skills | Essential |
| Ability to use initiative and think logically or laterally to resolve problems | Essential |
| Ability to lead and motivate a team | Essential |
| Ability to mentor and train less experienced staff | Essential |
| Ability to prioritise own work | Essential |
| Ability to work with minimal supervision | Essential |

Experience

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| Demonstrable experience in oncology clinical trial management at sponsor level. | Essential |
| Experience of working to deadlines and organising own workload | Essential |
| Experience of clinical trials data management | Essential |
| Experience of the central management of multi-centre clinical trials | Essential |
| Demonstrable experience of clinical trial monitoring and clinical trial site management | Essential |
| Experience of clinical trial reporting to stakeholders (e.g. oversight committees, funders, regulatory, ethics) | Essential |
| Experience of giving oral presentations | Essential |
| Experience of working on studies involving collection of biological samples | Essential |
| Experience of managing Phase I clinical trials | Essential |
| Line management experience | Essential |

General

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| Flexible and adaptable approach to managing workload | Essential |
| Willing to travel on occasion | Essential |

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 28 days per annum on joining. This will increase by a further day after 2 years’ and  
5 years' service.

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 the recruiting team by emailing [ddu-iit@icr.ac.uk](mailto:DDU.IIT@icr.ac.uk). This job description reflects the current position and is subject to review and alteration in detail and emphasis in the light of future changes or development.

Benefits