ICR The Institute of Cancer Research

Head of Investigator Initiated Trials Unit

Candidate Information

March 2025

The Institute of Cancer Research

About our organisation

The Institute of Cancer Research (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 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.

Our mission is to make the discoveries that defeat cancer.

Drug Development Unit

The Drug Development Unit (DDU), within the ICR is one of the leading Phase I clinical trials units in the world. The DDU, led by Professor Johann de Bono and Professor Udai Banerji, delivers both academic and industry-sponsored first-in-human and early phase oncology clinical trials. The DDU 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 at The ICR, or developed by CRUK scientists, or industry collaborators, in order to rapidly impact the care of cancer patients. The DDU has been involved in the development of many hundreds of novel agents including several practice-changing cancer drugs. The DDU operates as a conduit, between laboratory research and

clinical research that is fundamental to the modern drug development process.

The DDU is one of the Experimental Cancer Medicine Centres in the UK, part of the CRUK Convergence Science Centre and the Early Phase Drug Development Theme within the ICR-RM NIHR Biomedical Research Centre (BRC). The DDU has multiple academic and industry collaborations both nationally and internationally, to optimally serve our patients.

The Investigator-Initiated Trials (IIT) Team, is a dedicated academic trials management team within the DDU, performs functions associated with sponsoring early phase trials including trial initiation, trial development, project management, trial monitoring, pharmacovigilance, database development, safety review and trials reporting. The 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 DDU conducts first-in-man phase I trials involving a range of targets, including growth factors or intracellular signalling, angiogenesis, apoptosis, epigenetics and DNA repair. All DDU trials are underpinned by extensive analyses of biomarkers, both predictive and pharmacodynamic.

The successful applicant will be responsible for leading the delivery of DDU's Investigator-Initiated, ICR and ICR/RM-sponsored, Phase I / early phase clinical trials.

Further information is available at:

ICR

www.icr.ac.uk | **Twitter** @ICRnews | **Facebook** www.facebook.com/theinstituteofcancerresearch

ICR-DDU

https://www.icr.ac.uk/research-and-discoveries/icr-divisions/clinical-studies/the-adult-drug-development-unit-at-the-icr-and-the-rm

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Candidate Information
Head of Investigator Initiated Trials Unit

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.

Candidate Information

Head of Investigator Initiated Trials Unit

Job description

Department / division:	Drug Development Unit / Division of Clinical Studies
Pay grade / staff group:	Competitive salary; negotiable based on expertise and skills
Hours / duration:	Full-time (35 hours per week), Monday to Friday.
Reports to:	Head of Operations, DDU
Accountable to:	Director and Co-Director of DDU
Line Management:	Deputy Head of DDU-IIT, Clinical Trial Programme Manager and/or staff at their equivalent grades
Main purpose of the job:	The post-holder will be responsible for leading the delivery of the DDU's Investigator-Initiated, ICR and ICR/RM-sponsored early phase oncology clinical trials, ensuring alignment with the unit's scientific strategy and operational objectives. This senior leadership position will oversee trial management throughout the life cycle of trials, clinical trial budgets/contracts, data management, pharmacovigilance, and regulatory compliance while embedding digital transformation strategies to enhance operational efficiency and data-driven decision-making. The role will provide strategic and operational leadership in managing the expanding DDU portfolio, ensuring adherence to legislative frameworks and Good Clinical Practice (GCP) guidelines. The post-holder will support the development and implementation of digital solutions to optimise clinical trial processes, oversee quality management systems, and lead a multidisciplinary team to ensure successful study execution within agreed timeframes and resources.

Candidate Information
Head of Investigator Initiated Trials Unit

Duties and responsibilities:

Strategic Leadership

- Develop a portfolio of transformational trials by engaging with Investigators in alignment with organizational strategies and available funding streams.
- Develop the DDU-IIT team, maintaining a core team of expert staff and building up longer-term viability of capacity for project management and monitoring.
- Provide a strategic vision for the DDU-IIT team to complement ICR/RM strategy and business plan, ensuring performance is in line with organisational requirements.
- Contribute to the overall leadership of the DDU by playing an active role in the senior management team, deputising for the Head of Operations when absent.

Operational Leadership

- Lead the execution of investigator-initiated trials, ensuring the integration of digital systems for real-time data tracking, compliance monitoring, and risk assessment.
- Oversee and direct clinical research operations to ensure studies are conducted to the highest standards and in compliance with ICH-GCP and UK legislation.
- Oversee the management of investigator-initiated trials, ensuring systems are established to monitor all aspects of study progress, including screening, recruitment, compliance, IMP management, pharmacovigilance and reporting.
- Oversee the development and use of electronic regulatory documentation and digital pharmacovigilance systems to enhance reporting accuracy and compliance.
- Prepare or oversee preparation of clinical study protocols in conjunction with Chief Investigator and relevant scientists.
- Oversee and support the generation of contractual agreements, ensuring arrangements for trial conduct are consistent across the portfolio and in compliance with sponsor and funder requirements and national standards for non-commercial research.
- Manage outsourcing activities across the portfolio, negotiating new and amended work specifications, budgets, payment schedules, and other documents that control the activities and performance of contract research organisations.
- Manage clinical trial finances including budget preparation, budget negotiations, income/expenses, invoice managements etc.
- Maintain appropriate trial finance management tools for the efficient delivery of trials to budgets.
- Communicate overall status, issues and recommendations to the DDU senior management team and industry stakeholders.

Managerial, Supervisory, Advisory Responsibilities

- Structure the DDU-IIT team with appropriate workforce planning and securing appropriate funding.
- Supervise all project management, monitoring, pharmacovigilance and data management activities undertaken within the DDU-IIT team.
- Oversee staff recruitment and development including objective setting, performance appraisal and training. Remain directly responsible for all such activities for the direct reports.

Candidate Information
Head of Investigator Initiated Trials Unit

- Organise appropriate training in project management and monitoring specific to DDU-IIT trials.
- Provide specialist advice on Phase I clinical trial operational, regulatory and governance matters to the wider ICR and RM.

Quality Assurance Leadership for Investigator-initiated Trials

- Lead on quality assurance activities under which individual trial conduct is monitored and reviewed, including managing the ongoing review of systems and processes in use within the DDU-IIT Team and the continual refinement of these to ensure greater efficiency, effectiveness and standardisation, also leading preparatory activities for regulatory inspections and audits.
- Oversee production of SOPs, guidance and template forms as required, ensuring the highest professional and ethical standards in terms of all clinical activities and that all work meets GCP, regulatory, legal and quality standards.

Governance and Compliance Expertise

- Maintain excellent working knowledge of changing regulatory requirements for trial conduct to ensure the DDU-IIT remains compliant with current legislative requirements.
- Provide specialist advice on the integration of digital tools in Phase I clinical trials, ensuring enhanced compliance, efficiency, and data security.
- Provide a source of Phase I trial expertise and participate in ICR and RM policy development in this area as required.

Collaboration and Engagements

Internal:

- Member of the DDU Strategy Committee which oversee the implementation of DDU's scientific and operational strategy.
- Member of the DDU-IIT's Clinical trials Management Group that oversees the trial portfolio.
- Member of the DDU-IIT's trial specific meetings such as SOP development, Regular Trial Management Meetings, Safety Review Committees, Trial Steering Committees etc and provide sponsor-level operational leadership and expertise to trial activities.

Institutional:

- Manage and strengthen formal collaborations with the ICR-CTSU maintaining efficient communications and streamlining working practices.
- Member of ICR-RM joint management groups, alongside the Head of Operations,
- Member of RM R&D SOP Overview Group which reviews and develops quality standards for trials activity across the joint ICR and RM institutions.
- Member of the RM R&D Risk Identification Group, providing Phase I expertise as part of the Quality Management System for the conduct of clinical research within the ICR/RM joint institutions by reviewing unit activity and individual trial performance to inform the audit programme and where necessary escalate areas of concern to the appropriate committee.

Candidate Information
Head of Investigator Initiated Trials Unit

National / International:

- Liaise with and maintain an effective working relationship with DDU's academic and industry partners.
- Establish and develop links with other ECMCs to maximise opportunities for knowledge transfer and collaboration on research projects.
- Support DDU-IIT investigators in presenting data at international conferences to promote the work of the DDU-IIT team and attract in new studies.

General duties

- Attend and contribute to the DDU monthly research meetings, departmental and IIT team meetings and Trial Manager meetings.
- Support and participate in departmental working groups, and be part of DDU leadership team.
- 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

Work Environment and Challenge

- This role carries considerable responsibility for quality standards and regulatory activities within the Unit, and for management of senior staff. Post-holder is expected to have high level of resilience and excellent problem-solving skills.
- May require international travel and flexibility in working hours, with potential for some remote oversight of all DDU-IIT systems.
- Responsible for supporting the implementation of ICR's security measures to protect sensitive clinical data while ensuring seamless digital operations across trial sites.

Direction/Supervision Received

- The post-holder will work under the supervision of the Head of Operations and remains accountable to Director and Deputy Director of DDU with a direct report to the Head of Operations.
- The post-holder is expected to plan meetings to discuss high level strategy, prioritisation and resource planning are supplemented by frequent informal meetings to address areas of contention and matters that require immediate attention.
- The post-holder is responsible for presenting significant information, challenges, and potential solutions to leadership team, ensuring transparency in decision-making. While final decisions rest with the leadership team, the post-holder must effectively communicate these decisions to the team as an unified directive, ensuring clarity and alignment across the organisations.

Candidate Information
Head of Investigator Initiated Trials Unit

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 stays.

This role would usually be office-based with some flexible working options, which are considered dependent on the business needs of the Unit.

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

Candidate Information
Head of Investigator Initiated Trials Unit

Person specification

Education and Knowledge

A graduate or post-graduate degree in biological sciences' discipline or an equivalent qualification	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	Essential
Expert knowledge of trial management systems and processes	Essential

Experience

Leadership at a senior level (i.e. management team or equivalent) within an academic, NHS or commercial clinical trials environment	Essential
Significant experience of strategic planning and management of clinical research in a senior role	Essential
Substantial experience in clinical project management, including all aspects of clinical study design, data handling and project management	Essential
Experience of leading high-level negotiations i.e. with pharmaceutical companies, sponsors, funding bodies, Chief Investigators	Essential
Demonstrable experience of clinical trial monitoring and clinical trial site management	Essential
Track record in providing expert advice and guidance on trials related issues	Essential
Substantial line-management experience including objective setting, appraisal, performance management, mentoring and supporting professional development	Essential

Skills

Ability to work accurately, with a strong attention to detail	Essential
Excellent organisational and time management skills	Essential
Ability to lead and develop scientific projects, and effective 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

Candidate Information

Head of Investigator Initiated Trials Unit

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 senior experienced staff	Essential
Ability to prioritise own work	Essential
Ability to keep adapting to growing needs of clinical trials, and remain flexible	Essential

Candidate Information

Head of Investigator Initiated Trials Unit

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 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 bindu.baikady@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.