ICR The Institute of Cancer Research

Programme Manager (Study Management)

Candidate Information

The Institute of Cancer Research

About the 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 and the Royal Marsden, 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.

The Unit, within ICR and RM, 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 our patients as quickly as possible.

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.

*"**Our values set out how each of us at the ICR, works together to meet our mission – to make the discoveries that defeat cancer.** They summarise our desired behaviours, attitudes and culture – how we value one another and how we take pride in the work we do, to deliver impact for people with cancer and their loved ones"*

Professor Kristian Helin

Chief Executive

Programme Manager (Study Management)

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Job description

Department / division: Drug Development Unit / Clinical Studies

Pay grade / staff group: Scientific Pay Grade 3

Hours / duration: Full time (35 hours per week)
Monday to Friday
Fixed term contract for 1 year

Reports to: Deputy Head of Operations

Accountable to: Head of Operations & Consultants

Main purpose of the job:

To operationally support the efficient delivery of clinical trials within DDU with a focus on leading the Study Management team

To directly line manage, provide appropriate training and to effectively support development of all staff members in Study Management team.

To oversee quality assurance and compliance of clinical trials throughout their life cycle. To address any shortfalls and provide appropriate training/ support where needed, promoting a culture of the highest quality in clinical trial delivery and strict adherence to legislation.

To ensure the Study Management team fully supports trial participants and assists with managing trial logistics to provide the best possible quality of service to DDU patients at all times.

To take initiative in implementing new ways of working and keep abreast of the latest developments within clinical trial management.

To actively contribute in DDU's team meetings, take initiatives in implementing DDU's strategies.

To work in close partnership with fellow Programme Managers within the team and provide appropriate cover when needed and continuously support each other towards effective study delivery across all delivery teams.

To provide cover for Deputy Head of Operations in addressing urgent matters in their absence.

To work in accordance with the philosophy, policies, and requirements of the DDU, Institute of Cancer Research (ICR) and The Royal Marsden (RM).

To represent DDU within the ICR, Royal Marsden and at External partner meetings

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Responsibilities and Duties:

Leadership

- The post holder is responsible for all operational clinical trial coordination activities within the DDU, throughout the life cycle of clinical trials conducted in DDU.
- The post holder must ensure all operational activities within the Unit are in support of patient well being and to ensure patients safety and well being are never compromised.
- The post holder is expected to support management of all DDU collaborators' (e.g. Sponsor, CRO, grant providers, NIHR, HRA etc.) expectations and contribute to strategic vision and unit's priorities, keeping DDU at the forefront of clinical research both nationally and internationally.
- The post holder is responsible to have complete oversight of team deliverables, and ensure SM team works in adherence to SOPs and to the highest standards as required by the Unit.
- The post holder is responsible to constructively work with DDU leadership team, and contribute towards achieving Unit's vision at all times.
- The post holder will work in partnership with other fellow Programme Managers to support broader operational activities of the unit. Tasks include but not limited to: support Deputy Head of Operations day-to-day unit service delivery, support investigation and resolution of queries and/or deviations within DDU as needed, and support management of clinical trial finances.
- The post holder will represent SM team and DDU at external meetings where required, including but not limited to: Royal Marsden Trial Coordinator meetings, Industry site feasibility/site selection visits.
- The post holders shall work closely with all other staff groups collaboratively and ensure trial activities are delivered according the protocol needs.
- The post holder is responsible to take initiatives is implementing new ways of working to continuously support innovative practices within clinical trial management
- The post holder is responsible to support changes in working practices and keep abreast with latest developments within UK regulations, NIHR & HRA requirements and expectations from DDU's grant providers.

Management of SM Team

- The post holder responsible for management of recruitment, induction, training, appraisals, performance management, workload & resource management of SM staff and any staff related matters within study management team.
- The post holder is required perform continual assessments of performance and yearly appraisals, encouraging staff to develop their knowledge and experience.

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- The post holder to produce and maintain a rota for outpatient clinics, radiology reviews and biopsy data on a weekly basis to ensure all team members are represented in an appropriate fashion.
- The post holder to act as point of contact for the SM team, leading and supporting problem solving as and when required by maintaining full visibility of trial activities by the team and review of monitoring letters, audit, and inspection reports for compliance.
- The post holder will represent the SM Team at DDU management meetings and complete any actions from meetings and incorporate any systematic changes into working practices including reporting back the progress made.
- The post holder is responsible to ensure all documents, databases, trial records are appropriately maintained in real time and ensure business continuity needs are not compromised.
- The post holder is responsible to ensue study management work in close partnership with data management, regulatory, trial set up and clinical teams.

Study Management Responsibilities

- The post holder is required to support all activities of Study Management team throughout the life cycle of clinical trials in DDU.
- The post holder is responsible to undertake trial set up, patient recruitment, trial delivery, trial close out and trial archiving tasks within SM team.
- The post holder is responsible for allocation of trials across the Study Management team, working alongside other Programme Managers within the unit to ensure efficient service delivery.
- The post holder to facilitate and oversee completion of unit specific reports by the Study Management team. They are expected to work closely with senior members of the DDU team in creating, maintenance, and interpretation of unit performance reports and metrics using various digital tools.
- The post holder is expected to support unit cost recovery activities of the Study Management team, working closely with the DDU Finance Manager.

Quality and Compliance Management

- Post holder is expected to work closely with DDU Deputy Head of Operations and report regularly on trial activities, trial status and any ongoing operational matters. Post holder must maintain an excellent document management processes as part of business continuity plan within the Unit.
- Post holder will work closely with the Operational (Deputy and Head of Operations), Clinical (Unit Consultants, Clinical Fellows), Nursing (Oak Ward Matron, Sisters, CNS, Practice Educators, Research Nurses, Ward Clerks) and Non-Clinical staff (Data Managers, Lab teams, Finance Manager, Regulatory team, Clinical Trial Strat Up Team, Pharmacy team) to continuously improve unit procedures and the quality of clinical trial coordination.
- To ensure the SM team manages clinical trials in compliance with clinical trials regulations, namely, The Medicines for Human Use (Clinical Trials) Regulations 2004 (2004 No.1031), The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (2006 No.1928) & Amendment (No.2)

Regulations 2006 (2006 No.2984) and The Data Protection Act (DPA) and General Data Protection Regulation 2018 (GDPR) and both acquire and maintain a high level of knowledge of current and forthcoming clinical trials conduct legislation through self-learning.

- The post holder is responsible to support any change in clinical trial legislation to be translated into the working practices of the unit, specifically relating to the SMs.
- The post holder is responsible to ensure that essential study documentation is available on eISF platform according to GCP including training, quality checking and maintaining staff competency, and regularly review all monitoring reports and troubleshoot, correct and resolve all issues effectively.
- In collaboration with the GCP Compliance Manager, to carry out routine audits of DDU documents and practices to ensure these are completed effectively and correctly as well as make an active contribution to the development of Standard Operating Procedures (SOP) relating to Clinical trial coordination and trial management. Support the GCP Compliance Manager to prepare for audits, inspections where required

General

- Communicate effectively, be respectful and courteous with all members of the team, unit and centre. To work in a flexible organized manner, meeting objectives and deadlines.
- To provide the best possible service to our patients, and collaborators (e.g. commercial and non-commercial sponsors, CRO's, grant funders etc.)
- To play a full and supportive role in contributing to and maintaining a cohesive study site function within the unit, contributing to best practice within the team.
- To assist with the preparation of research papers as requested, and/or the collection of data required for publication/presentation of research studies.
- To adhere to the regulatory rules and safety regulations of the ICR and The RM.

Confidentiality

- All information concerning patients and staff must be held in the strictest confidence in line with the General Data Protection Duty guidelines and must not be divulged to any unauthorised person at any time, unless to do so is in the best interest of the individual. In these scenarios a Senior Team Member's consent will be sought and recorded for compliance.
- Computer data should only be accessed if this has been authorised and is necessary as part of your work.
- The post holder must abide by the requirements of the General Data Protection Regulation 2018 (GDPR) at all times.
- Any other duties may be required that are consistent with the nature and grade of the post.

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

Person Specification

Education and Knowledge

A science or health - related higher education qualification	Essential
A good understanding of medical terminology, clinical pharmacology and the clinical trial process	Essential
Knowledge of EU and UK Legislation surrounding clinical trial conduct to GCP, and UK Research Governance	Essential
A good understanding of Oncology and Phase I Clinical Trials	Essential

Experience

Experience at a Clinical Trials investigator Site	Essential
Proven experience of working on multiple studies, study sponsors, CROs and CRAs	Essential
Proven Experience of working in accordance with ICH-GCP regulatory standards for the conduct of clinical trials and UK Research Governance	Essential
Experience in line management and leading a large team of clinical trial technical staff members	Essential
Demonstrable experience in change management	Essential
Demonstrable experience in managing high volume of complex clinical trials, prioritization and maintaining GCP compliance	Essential
Demonstrable experience in taking initiatives to implement, maintain and adapt to new ways of working	Essential
Demonstrable experience in leading a team, supporting staff development and enhancing team output	Essential
Demonstrable experience with organisational aspects surrounding clinical trials	Essential
Contact with patients suffering from terminal disease	Essential

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Skills

Excellent planning skills, ability to prioritise effectively	Essential
Excellent ability to manage trial logistics and variety of tasks at any given time	Essential
Effective verbal and written communication skills	Essential
A methodical approach and attention to detail	Essential
Highly organised, ability to adapt to a dynamic clinical environment	Essential
Excellent interpersonal skills and a confident, caring approach to patients and their families	Essential
Good IT skills, proficient with the use of MS Office applications	Essential

General

The ability to adapt to a dynamic clinical environment	Essential
An interest in cancer and drug development.	Essential
The desire to develop their skills further for the benefit of the DDU.	Essential

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

If you require further information, please contact us by email ddu@icr.ac.uk

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