ICR The Institute of Cancer Research

Senior Study Manager

Candidate Information

The Institute of Cancer Research (ICR)

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 out 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

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Job description

Department / division: Drug Development Unit / Clinical Studies

Pay grade / staff group: Scientific Pay Grade 4 / Research Management 3

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

Reports to: Study Management (SM) Team Lead and Deputy Head of Operations

Accountable to: Head of Operations and Consultants

Main purpose of the job:

The Senior Study Manager (SSM) is responsible for independent management of assigned clinical trials, at site, to the highest standard. The SSM is also responsible to provide full clinical trial project oversight for a portfolio of studies, as required.

The SSM is responsible for efficient set up, patient recruitment, patient management, review, and implementation of amendments, close out, and project management of clinical trials at site level throughout the life cycle of assigned trials ensuring effective communication with all support services.

The SSM must be able to manage several complex studies at the same time with clear communication and organisation skills. The SSM must ensure excellent flow of information across all clinical team and must have oversight of all clinical trials in their portfolio.

The SSM is responsible to take initiative to resolve all study related matters with site staff, CRO and study sponsor to ensure trials run smoothly within DDU, maintaining compliance to SOPs and DDU practices.

The SSM will work with Study Management team lead in transformation activities and take initiative in transitioning team into modern workplace. The SSM must adapt and lead the team with constantly changing trial requirements.

The SSM is responsible to train and line manage Clinical Trial Assistants, Assistant Study Managers and Study Managers.

The SSM is responsible to fully cross cover other SSMs and SM team, and deputise SM team lead, during their absences, in DDUOG, CTRMG, pre-screening MDT and trial meetings; representing study management team.

Responsibilities and Duties:

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Clinical Trial Set-up and Delivery

- To review the clinical study protocols to assess the operational requirements in setting up the study. Where required, the SSM will attend CTRMG and contribute to Protocol review during early stages of trial set up.
- To coordinate the necessary set-up activities within the unit, ensuring that all aspects of the protocol has been address, all team members are aware of their responsibilities and trials are opened in timely manner.
- To liaise with finance teams to support creation, training and maintenance of finance data activity capture tools supporting income capture and income recovery. Assist the finance team in capturing patient visit activity using finance data activity capture tools, coordinating patient expense claims, raising invoices, and liaise with sponsors when required.
- To liaise with clinical trial participants and provide all required support to ensure smooth delivery of trials.
- To ensure all trial activities are completed in a timely manner, liaising with all support services. The SSM is expected to proactively support patient needs and ensure they are able to start trial as soon as possible.
- To actively contribute to all weekly meetings ensuring the logistical and operational items are brought for discussion.
- To plan and review trial needs regularly, address any findings with appropriate CAPA. To engage with open and transparent communication across the team to enhance team output.
- To work with the study team to ensure that trials run in accordance with the protocol, sponsor guidelines and relevant UK clinical trials regulations.
- To ensure that essential study documentation is available on site ISF/ eISF platform according to GCP, regular filing is expected. To ensure all trial documents are maintained within shared folders in a timely manner.
- To liaise with the allocated Data Manager to ensure that Case Report Form completion and query resolution meets sponsor deadlines and is of the required standard.
- To maintain business continuity for all activities ensuring there is full audit trail of trial activities. To provide back up for essential activities.

Patient Recruitment Management

- Liaise with the sponsor and PI to determine study status and number of available slots.
- To attend the Patient Allocation Meeting, tasks include but not limited to: communicating slot availability information, advice on specific eligibility criteria and relay any study pertinent specific information.
- In liaison with the Clinical fellow/Co-investigator for the study, ensure the patient is potentially eligible for the trial prior to provision of study patient information sheets.
- To regularly attend teleconferences / safety meetings, keep records of minutes and circulate/make accessible for relevant staff.

- When required and appropriate undertake patient informed consent for non-IMP trials and/or biomarker screening processes.

Internal and External Liaison

- To liaise with sponsors and sponsor representatives throughout the clinical trial life cycle and communicate all key matters to study teams in a timely manner.
- To liaise with all site teams and communicate in a clear & concise manner.
- To understand and be able to explain to patients details of their specific clinical trial, such as, the required schedule of hospital appointments, required clinical assessments and blood sampling requirements.
- To liaise with, and support patients and their families through the trial procedures.
- To attend outpatient clinics on rotation to support the smooth running of clinics.
- To liaise with pathology departments across the UK to obtain archival tumour samples for mutational analysis on patients referred to the unit for consideration of Phase I trials. To manage the collection, maintenance and returns of all archival tumour samples coming into the unit.
- In collaboration with team colleagues, explore and adapt innovative ideas to simplify the challenges of conducting Clinical Trials to maintain effective communication with internal and external departments.

Leadership

- Deputise Study Management team lead especially during their absence, to ensure service continuity. Tasks include but not limited to: attendance in relevant senior meetings (e.g. DDUOG, CTRMG, representation for SM team), assist in reviewing study protocols, provide feedback and comments at feasibility stages and, attend the Clinical Trial Risk and Management Group (CTRMG), resource review and operational process development for the SM team, attend study budget negotiation meetings and assist in developing study costs, assist in providing ad-hoc operational support when needed, support training junior members of the team and support digital transformation activities.
- Assist in reviewing existing and/or developing relevant Standard Operating Procedures promoting a culture of compliance and strict adherence to clinical trials regulations. Proactively work with staff, leading by example, demonstrating teamwork, showing kindness and respect to all.

Line Management

- The SSM will be directly responsible for overseeing and mentoring of Clinical Trial Assistants, Assistant Study Managers and Study Managers.
- The SSM will be involved in recruitment, training and managing induction of junior staff, tasks include but not limited to: undertake probationary review, annual review, oversight of staff performance, any performance review as per institutional practices, and staff re-training.

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General

- To communicate effectively with other members of the team as well as internal and external collaborators, maintaining a cohesive study site coordination function within the unit. To also represent and promote DDU at external meetings/conferences.
- To attend routine team operational meetings regularly, including chairing the meeting and minute taking on a rota basis. To work in a flexible manager and be organized to meet efficiency metrics and deadlines.
- To assist finance teams with income recovery process for industry sponsored trials.
- To develop extensive knowledge of, and comply at all times with the EU and UK Legislation for clinical trial conduct, RM Trust Level SOPs and local DDU procedures. Also providing troubleshooting/problem solving approach to issues.
- To assist with the preparation of research papers as requested, and/or the collection of data required for publication/presentation of materials.
- To adhere to the regulatory rules and safety regulations of the Institute of Cancer Research and Royal Marsden Hospital

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. 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.

  As the SSM progresses within the role, s/he will be provided with opportunities to gain experience in other activities, which will support their own development and that of their team.

  Any other duties that may be required which 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.

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Person Specification

Education and Knowledge

Educated to degree level in life sciences or nursing	Essential
Comprehensive working knowledge of The Data Protection Act (DPA) and General Data Protection Regulation 2018 (GDPR).	Essential
A thorough understanding of medical terminology, clinical pharmacology and the clinical trial process	Essential
Knowledge of the specific requirements of complex Phase I oncology studies	Essential

Experience

Proven experience of working on phase I or similar oncology clinical trials or experience of Phase I oncology data management in the phase I setting	Essential
Proven experience of working on multiple studies, study sponsors, CROs and CRAs	Essential
Experience of working in accordance with ICH-GCP regulatory standards for the conduct of clinical trials and UK Research Governance	Essential
Experience of working at an Investigator Site	Essential
Contact with patients suffering from terminal disease	Essential
Demonstrable experience of mentoring and line management	Essential
Demonstrable experience working in Change Management	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
Excellent IT skills, proficient with the use of MS Office applications	Essential

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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 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 email ddu@icr.ac.uk .

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