ICR The Institute of Cancer Research

Assistant Study Manager

Candidate Information

August 2025

The Institute of Cancer Research

About our organisation

We are one of the world's most influential cancer research institutes with an outstanding record of achievement dating back more than 100 years. We are world leaders in identifying cancer genes, discovering cancer drugs and developing precision radiotherapy. Together with our hospital partner The Royal Marsden, we are rated in the top four centres for cancer research and treatment worldwide. As well as being a world-class institute, we are a college of the University of London.

We came second in the league table of university research quality compiled from the Research Excellence Framework (REF 2021). We have charitable status and rely on support from partner organisations, charities, donors and the general public.

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We have more than 1000 staff and postgraduate students across three sites – in Chelsea and Sutton.

Adult Drug Development Unit | Clinical Studies

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

Assistant Study Manager
Candidate Information

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.

The Job role

The Assistant Study Manager (ASM) is responsible for the Operational management of Phase-1 clinical trials run in the DDU and to assist Study Managers in delivering clinical trials.

Our mission is to make the discoveries that defeat cancer.

Assistant Study Manager
Candidate Information

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

Assistant Study Manager
Candidate Information

Department / division:	Drug Development Unit / Clinical Studies
Pay grade / staff group:	Research Management 1
Hours / duration:	Full time (35hours per week), Monday to Friday. Fixed term contract for 1 year
Reports to:	Lead Study Manager
Accountable to:	Consultants, Head of Operations, Deputy Head of Operations
Main purpose of the job:	The Clinical Assistant Study Manager (ASM) is responsible for the management of assigned clinical trials at site. The ASM is responsible for planning, scheduling, and arranging all study related activities according to Protocol requirement. The ASM is responsible for efficient, study recruitment, study close out and, project management of clinical trial at site level. The ASM is responsible to act on study amendment requirements for assigned studies and work with the start-up team to ensure efficient implementation of the amendment at site. The ASM is responsible to ensure that early phase clinical trials are managed in compliance with the EU Directive 2001/20/EC and GCP Directive 2005/28/EC, according to the protocol, sponsor requirements and RM policies. The ASM is responsible for managing several studies at the same time and will be responsible to communicate key information to both the clinical and non-clinical study teams (clinical fellow, trial nurse, data manager, pharmacy and laboratory technicians), leading the study team and ensuring a satisfactory flow of information to all parties. The ASM is responsible to take initiative and resolve all study related matters with site staff, Contract Research Organisations (CRO) and the study sponsor to ensure trials are run smoothly within the DDU.

Assistant Study Manager
Candidate Information

Job description

The ASM is also responsible for managing all the patient's trial-specific appointments and investigations in line with the protocol.

The ASM is responsible for completing their work in a timely manner.
To support, cover and assist the Biological Specimen Coordinators

Duties and responsibilities:

Assistance to Study Manager

To assist the study team in screening patients & ensuring all documents are appropriately completed and filed in timely manner.
To assist the DDU with printing, scanning, photocopying and uploading study related documents to sponsors and vendors.
To provide support to the study team with the filing of study documents in Investigator Site Files and patient related study files.
To provide support to the study team in preparing trial folders and filing essential documents in trial folders.
The collection of clinical trial records (case notes, medical notes etc.) as needed for screening, monitoring and audit purposes.
To support the research team with transport of essential documents between ward and offices and collection of essential signatures from site staff.
To support the study team with preparations for sponsor / external audits or regulatory inspections.
To work with the study team towards archiving study documents
To support the Study Management team for holiday cover and attending to essential trial management tasks.
To support the team in shipping study related materials.
To support the team in completing study specific forms, if required.
To work independently using your own initiative (Site staff are available as a point of reference for any queries and will meet regularly).

Study Management

To independently manage clinical trials that are less complex and/or open due to long term patient responses
To undertake all study related activities and ensure the smooth running of assigned studies.

Assistant Study Manager
Candidate Information

To ensure all study documents are updated in line with any amendments or safety updates.
To maintain study records for business continuity and maintain visible audit trail of all trial activities.
To provide appropriate handovers for holiday planning.

Patient Recruitment

To manage the recruitment process for assigned studies that are less complex.
Liaise with the sponsor and PI to determine study status and number of available slots.
Communicate slot availability and advise on specific eligibility criteria at the Patient Allocation Meeting (PAM).
In liaison with the Clinical fellow/Co-investigator for the study, ensure the patient is potentially eligible for the trial prior to issuing the patient information sheets.
To attend the PAM meeting, take notes for their own studies and relay any study specific information to the team at team meetings.
To attend teleconferences / safety meetings and circulate meeting minutes to the team.
Keep records of safety meeting minutes and ensure these are made accessible for the relevant staff.

Patient Registration, Screening and Treatment

Liaise with potential study participants, and ensure that the patient receives the patient information sheet for the trial that they are allocated to and annotate in Electronic Patient Records system.
To prepare the appropriate informed consent documents for the patient's consenting clinic visit and pass the GP letter to medical secretaries.
Liaise with the patient and clinical staff to arrange all screening procedures, treatment dates, follow up visits and investigations required by the protocol.
To ensure that blood form requests are prepared in advance of patient visits and ensure that the clinical staff seeing the patient are informed at all times as to the requirements of the protocol.
To ensure all relevant screening activities are completed prior to registering patients onto trials. Liaise with study teams to ensure the external results are appropriately received and reviewed prior to registering patients.
Must review Incl. / Excl. checklist completion and then register patients with sponsors once the inclusion/exclusion criteria have been satisfied.
To maintain all registration documents as per trial requirement.
Pre-order trial medications for each patient's treatment visits.
Update monthly trial DVTs and check against actual trial visits.

Assistant Study Manager
Candidate Information

Assist the finance team in coordinating patient expense claims, check against actual trial visits and liaise with sponsors as and when required.
Assist with preparations for weekly review of patients' disease assessments.
Ensure Molecular Characterisation worksheets are completed for each patient visit. Cover molecular characterisation coordinator if needed.

Trial Conduct

To work with the study team to ensure that trials run in accordance with the protocol, sponsor guidelines, DDU SOP's, the EU Directive 2001/20/EC and the GCP Directive 2005/28/EC.
To ensure that the current protocol, amendment and patient information sheets are available to the clinical team at all times, and that they are aware of any changes.
To work with the Study Start-up team when there are protocol amendments and implement any resulting changes in study procedures.
To ensure that all necessary supplies needed for trials are available at all times for the trial nurses and laboratory staff.
To ensure that essential documentation is retained in the Investigator Trial Files as required by DDU, the sponsor and according to GCP.
To ensure regular electronic filing of essential documents.
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 ensure that any issues arising from routine monitoring visits that may affect the conduct of the study are discussed and resolved in a timely manner.
To manage the collection, maintenance and return of archival tumour blocks coming into the unit for responsible trials.
To maintain trial trackers are up to date at all times, ensuring that all patient visits and assessments are tracked for invoicing purposes.

Internal & External Liaison

To collaborate with sponsor representatives to manage each trial, acting as the main point of contact for the sponsor and ensuring that studies meet agreed targets.
To lead the in-house study team, resolve any queries regarding trial conduct, or to communicate these requests to the correct clinical trial personnel.
To attend trial specific teleconferences with the sponsor.
To organise and chair study team meetings as required for the smooth progression of each study, ensuring each team member has a clearly defined role and understands their responsibilities for the trial.

Assistant Study Manager
Candidate Information

To attend weekly DDU meetings for Patient Allocation and On Trial Patient discussions.
To ensure all relevant DDU personal are informed weekly of patients having biopsies.
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, as required.
To liaise with the laboratory team to ensure there are enough trial kits, and the correct kits are used at each occasion. In collaboration with the lab team, to organise shipment of blood samples and biopsy samples routinely.
To provide back up support to the team members on critical activities during holiday periods and/or emergencies.
In collaborate 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.
To act as a point of contact and facilitate effective communication.
To participate in internal regulatory meetings.
To attend teleconferences related to regulatory work.
To take initiative in preparing the site for Audits and Inspections.
To support the team in preparations for Audits and Inspections.
To promptly and timely maintain all regulatory documents at site level

General

To communicate effectively with other members of the team and the centre.
To attend routine Study Manager Meetings regularly, including chairing the meeting and minute taking on a rota basis.
To provide a troubleshooting/problem solving approach to ensure study issues are resolved effectively.
To play a full and supportive role in contributing to and maintaining a cohesive study site coordination function within the unit, contributing to best practice within the team.
To represent and promote the DDU at external meetings/conferences and present information as required.
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.
To assist with the preparation of research papers as requested, and/or the collection of data required for

publication/presentation of materials.
To work in a flexible manner and be organised to ensure timely completion of objectives by the agreed deadlines.
Prepared to perform other duties as required, which are consistent with the grade of the post.
To adhere to the regulatory rules and safety regulations of the Institute of Cancer Research and Royal Marsden NHS Foundation Trust.
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
Any other duties that are consistent with the nature and grade of the post that may be required.
To work in accordance with the ICR's Values.
To promote a safe, healthy and fair environment for people to work, where bullying and harassment will not be tolerated.
Post holder may undertake any other work in line with the pay grade and as required for the team
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.

Confidentiality

All information concerning patients and staff must be held in the strictest confidence and may not be divulged to any unauthorised person at any time, unless to do so is in the best interest of the individual. In this instance a Senior Team Member would appropriately advise the post holder.
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 Data Protection Act at all times.

Assistant Study Manager
Candidate Information

Person specification

Education and Knowledge

At least A level or equivalent	Essential
Educated to degree level in health sciences or nursing	Essential
Comprehensive working knowledge of GCP (EU Directive 2001/20/EC and GCP Directive 2005/28/EC)	Essential
A thorough understanding of medical terminology, clinical pharmacology and the clinical trial process	Desirable
Knowledge of the specific requirements of complex Phase I oncology studies	Desirable

Experience

Experience of working in a health-related area	Essential
Proven experience in maintaining efficient filing systems and document management	Essential
Proven experience of working on Phase I or similar oncology clinical trials or experience of Phase I oncology data management in a Phase I setting	Essential
Proven experience of working on multiple studies, study sponsors, CROs and CRAs	Desireable
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	Desireable
Contact with patients suffering from terminal disease	Desireable

Skills

Good logistical and planning skills, ability to prioritise effectively	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
Problem solving and taking initiative to resolve study related matters	Essential
Working together with multi-disciplinary team and supporting to deliver organisational Strategies	Essential
Excellent IT skills, proficient with the use of MS Office applications	Essential

Assistant Study Manager
Candidate Information

Person specification

General

Excellent interpersonal skills to engender successful working relationships and communication with colleagues and trial collaborators	Essential
Excellent organisational skills and time management skills, able to meet competing Deadlines	Essential
Effective oral and written communication skills, with the ability to communicate complex information to a range of audiences	Essential
An interest in cancer and drug development	Essential
The desire to develop his/her skills further for the benefit of the team	Desireable

Assistant Study Manager
Candidate Information

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. All staff receive an additional three days at Christmas.

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 Lydia Turner for further information by emailing ddu@icr.ac.uk. 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.