Clinical Data Manager
Candidate Information

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 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

Our mission is to make the discoveries that defeat cancer.

Clinical Data Manager

Candidate Information

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.

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Clinical Data 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

Clinical Data Manager
Candidate Information

Job description

Department / division:	Drug Development Unit / Clinical Studies
Pay grade / staff group:	Research Management 1
Hours / duration:	Full time (35 hours per week) Monday to Friday Fixed term contract for 1 year
Reports to:	Lead Data Manager Senior Data Manager
Accountable to:	Head of Operations, Consultants, Lead Data Manager & Senior Data Manager
Main purpose of the job:	To be responsible for ensuring the accurate collection, collation and transcription of clinical data generated in early clinical trials. To maintain study specific documents within the team. To address and resolve study related queries with sponsors and meet study data locks. To maintain study specific databases and generate weekly reports To work with seniors members of the team to set up a new study within the Drug Development Unit (DDU). To play an integral role as a member of clinical trials teams within the Drug Development Unit for the conduct, co-ordination and recording of Phase 1 Clinical Trials alongside a Consultant Principal Investigator, Clinical Fellow/Sub-Investigator, Study Manager, Regulatory Trial Co-ordinators and Nurses. To be responsible for ensuring the accurate collection, collation and transcription of clinical data generated in early clinical trials. To maintain study specific documents within the team. To address and resolve study related queries with sponsors and meet study data locks.

Clinical Data Manager
Candidate Information

Job description

To maintain study specific databases and generate weekly reports

To work with seniors members of the team to set up a new study within the Drug Development Unit (DDU).

To play an integral role as a member of clinical trials teams within the Drug Development Unit for the conduct, co-ordination and recording of Phase 1 Clinical Trials alongside a Consultant Principal Investigator, Clinical Fellow/Sub-Investigator, Study Manager, Regulatory Trial Co-ordinators and Nurses.

Responsibilities and Duties:

Generation of Data Collection Tools

- Design, develop and maintain Clinical Trial Data Collection tools.
- Design of Patient Care Plans in accordance with trial protocol using MS Office packages, to meet data collection needs from clinical studies.

Patient History Collection & Research

- To fully research and collate with doctors and the primary trial team to collect source documents and information in order to capture a detailed history of patients' disease and care.
- To contact external institutions where this information is not available.

Liaison with representative from Sponsor Companies

- To act as a point of contact for the sponsor to resolve data related queries including adverse events, concomitant medications, administrative tasks with SAE reporting, data locks, deadlines, delegation of duties and training logs.
- To assist the Pharmaceutical Company representatives with Source Data Verification, or Clinical Data Queries as required by ICH GCP.

Clinical Data Manager
Candidate Information

Study related document maintenance

- To maintain study specific Investigator Site File in an organised manner.
- Ensure Version control is maintained for study documents used in Data Management.
- Ensure study documents are appropriately scanned and filed in electronic shared folders in a timely manner.
- To arrange with Pharmacy, the collection of drug accountability documents and retain them with other source documents.
- To print lab results for review by the trial investigator and keep them in the source document folder in a timely manner.
- To keep a close eye on the regulatory emails for any amendments and their implementation, in order obtain training documents from the study team.
- To obtain signatures from study personnel on key documents, such as the Delegation of Duties Log, Data/financial disclosure forms, Investigator commitment documents, training documents etc.

Maintenance of the Drug Development Unit Database

- To update the DDU database that holds patient and trial information, for the purpose of day to day organisation of the DDU
- To include patients newly referred to the DDU to ensure that they are considered for inclusion in a clinical trial.
- Utilise the database to create weekly reports that form the basis of the multidisciplinary team meetings, and communicate patient and time specific detail to the other members of the DDU.

Communication of clinical information to Trial Sponsors

- To accurately complete Case Report Forms provided by the Sponsor for the collection of clinical trial information.
- To ensure that patient confidentiality rights are upheld.
- To assist with and monitor reporting of Serious Adverse Events (SAE) in accordance with ICH GCP.
- To request monitors access to the RMH computer network and electronic patient record (EPR).
- To liaise with monitors to arrange monitoring visits.

Clinical Data Manager
Candidate Information

Ensure clinical trial record retention

- To ensure that all necessary clinical trial documentation is archived in accordance with GCP regulatory requirements, in a timely manner.
- To ensure that trial specific patient information is archived in accordance with Royal Marsden policy and anonymous trial specific information archived in accordance with GCP until no longer required.

Clinical Trial Coordination

- To attend weekly departmental meetings regarding clinical trial status and medical care of participating patients.
- To attend trial specific teleconferences when required.
- To take minutes from meetings and circulate notes on a pro rota basis.

New Study set up

- Work under the supervision of Senior Clinical Data Managers to set up a new study.
- To work in a flexible manner, be organised, meet data management objectives and work to meet the stringent study deadlines.
- To adhere to the regulatory rules and safety regulations of the Institute of Cancer Research.
- Work with the team towards setting up site initiation visit (SIV), attend SIV, and complete all relevant training to work on the study.
- Keep track of the delegation that are allocated to the trial, to ensure no one is missed from the training and delegation of duties log.

Administrative tasks with Serious Adverse Event (SAE)

- Working on all the administrative activities associated with SAE reporting, and communicating with the study sponsor in a timely manner.
- To work with Investigators to ensure timely reporting of all SAEs and resolve SAE related queries with priority.
- To maintain SAE forms, to file in ISFs, and scan them to the shared drive under study folder.

Clinical Data Manager
Candidate Information

SUSAR Reports

- To keep a copy of the SUSAR report in the site file, and to report the SUSAR report to local R&D if applicable, after being reviewed by the principal investigator.

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- To maintain SAE forms, to file in ISFs, and scan them to the shared drive under study folder.

General

- To communicate effectively with other members of the team and the centre.
- To work in a flexible manner, be organised, meet data management objectives and work to meet the stringent study deadlines.
- To adhere to the regulatory rules and safety regulations of the Institute of Cancer Research.

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.

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.

Clinical Data Manager
Candidate Information

Person specification

Education and Knowledge

Educated to GCSE Level standard including Mathematics, English, and Science	Essential
A health-related higher education qualification or Experience in Clinical Trials or extensive experience in healthcare administration	Essential
A good understanding of medical terminology	Essential
Knowledge of Good Clinical Practice and appropriate EU/UK regulations	Essential
Knowledge of Clinical Trials and Clinical Pharmacology	Desirable

Experience

Experience at a clinical trials investigator site or extensive experience in healthcare administration	Essential
Experience in Oncology Clinical Trial Data Management	Desirable
Development of data acquisition forms and collation of clinical data	Desirable

Skills

A methodical approach, the ability to pay attention to detail	Essential
Computer literacy in Microsoft Office or equivalent	Essential
The ability to work independently within a team environment	Essential
Clear, legible handwriting	Essential
The ability to organise work and time around a dynamic clinical unit	Essential

Clinical Data Manager
Candidate Information

Person specification

General

Excellent organisational and interpersonal skills	Essential
Good written and verbal communication skills	Essential
Initiative and ability to think logically or laterally to resolve problems	Essential
Attention to details and Ability to maintain quality	Essential
The ability to work independently, and 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 Drug Development Unit	Desirable

Clinical Data 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.

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, you may contact Lydia Turner by emailing ddu@icr.ac.uk .

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