Scientific Officer - Pharmacy Research Coordinator

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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 top in the league table of university research quality compiled from the Research Excellence Framework (REF 2014).

We have charitable status and rely on support from partner organisations, charities, donors and the general public.

We have more than 1000 staff and postgraduate 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-1 Clinical Trials Unit in the world. The Unit, led by Professor Johann de Bono, comprises of Clinicians, Research Nurses, Pharmacists, Scientists and administrative support staff.

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 operates as a conduit, between laboratory research and clinical research that is fundamental to the modern drug development process.

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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Department / division:	Drug Development Unit / Clinical Studies
Pay grade / staff group:	Scientific Officer
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:	DDU Pharmacist, DDU Head of Operations and DDU Consultants
Main purpose of the job:	The Pharmacy Research Coordinator is responsible for providing support to the Drug Development Unit (DDU) Pharmacist. To provide assistance with trial set up, trial amendment management and trial related document review. To assist with IMP management, internal and external communications. To support coordination of Pharmacy workflow, maintain data within Pharmacy trackers, logs & databases for the clinical trials running in DDU. To assist with Investigator Initiated Trial Protocol review and provide input towards content development

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Duties and responsibilities:

Clinical Trial Management and Coordination

- To work alongside DDU Pharmacist to ensure all trial related documents are received by Pharmacy
- To assist DDU and DDU Pharmacy team to maintain trial specific logs of set up activities
- To review clinical trial Protocols and identify site requirements to set up DDU clinical trials
- To review Pharmacy Manual and work alongside DDU team to open clinical trials in a timely manner
- To assist Pharmacist in addressing pharmaceutical issues relating to medicines management within the DDU, ensuring adherence to national guidelines and medicines legislation.
- To assist Pharmacist in assessing Pharmacy capacity and resource needs to deliver the trials
- To assist Pharmacist in liaising with DDU, R&D and other support services
- To ensure all trial related documents are on site prior to trial opening
- To assist DDU Pharmacist in setting up trial budget, trial validation activities
- To assist DDU pharmacist in evaluating investigator-initiated trial protocols, and contribute to CCR review
- Liaise with the pharmacy aseptic, dispensary and clinical teams and the multidisciplinary team to ensure an efficient, effective and safe pharmacy clinical trials service is provided
- To Identify any systematic or preventable errors associated with medicines used within the DDU and work closely with the medical and nursing team to find solutions and minimise risk of Recurrence
- To maintain pharmacy clinical trial database for activity and support the Lead Pharmacist, Clinical R&D to produce the trial activity quarterly report, identifying any capacity issues and resource requirements and highlighting any areas of potential cost saving
- To proactively support clinical trial monitoring activities by providing required documents for review and verification
- To proactively maintain Trial specific ISFs and support internal and external Audit processes
- To support DDU in digital transformation activities
- To support Pharmacy in administrative activities required to manage clinical trial amendments

Clinical Trial Team Meetings

- To actively participate in regular DDU and Pharmacy team meetings, and provide required updates
- To join sponsor meetings, Site Initiation Visits and Monitoring visits and address Pharmacy action items with input from Pharmacist
- To attend weekly prioritisation meetings with research nurses and ensure Pharmacy team is kept informed of priorities
- To attend sponsor meetings / external meetings to support smooth delivery of clinical trials

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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 trial administrative activities

- 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 work within 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.

Communication of clinical information to Trial Sponsors

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

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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.
- Ensure all relevant training have been completed in a timely manner
- Maintain an up do date CPD portfolio

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 deta and emphasis in the light of future changes or development.

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Person specification

Education and Knowledge

Educated to GCSE Level standard including Mathematics, English, and Science	Essential
A health-related higher education qualification or A qualification in Pharmacology or Pharmacy related subjects	Essential
A good understanding of medical and pharmaceutical terminology	Essential
Knowledge of Good Clinical Practice and appropriate Clinical Trial guidelines	Essential
Knowledge of Clinical Trials and Clinical Pharmacology	Desirable

Experience

Experience in Clinical Trials or extensive experience in healthcare administration	Essential
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

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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

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

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