ICR The Institute of Cancer Research

Clinical Trial Manager
Candidate Information

June 2022

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.

The Trial Manager will have responsibility for a portfolio of trials related to the development of the magnetic resonance linear accelerator (MR LInac; Elekta Unity ®). As such the post holder will need to work with clinical and non clinical staff across the Department of Radiotherapy in a number of clinical units.

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:	Radiotherapy and Imaging
Pay grade / staff group:	Scientific Professional 5/Higher Scientific Officer
Hours / duration:	Part time (21 – 26.25 hours per week). Fixed term contract for 14 months.
Reports to:	Kelly Jones, Clinical Research Unit Operations Manager
Main purpose of the job:	The role of the Clinical Trial Manager is to ensure all clinical trials in their area of responsibility are conducted and managed in accordance with Good Clinical Practice and Trust and Institute of Cancer Research SOPs. The Trial Manager will have responsibility for a portfolio of trials related to the development of the magnetic resonance linear accelerator (MR LInac; Elekta Unity ®). As such the post holder will need to work with clinical and non clinical staff across the Department of Radiotherapy in a number of clinical units. The post-holder must be able to manage a number of studies at the same time and will be key to communication within clinical and non-clinical study teams.

Duties and responsibilities:

CLINICAL TRIAL RESPONSIBILITIES

Trial Set-Up
Review the clinical study protocol to assess the operational requirements in setting up the study.
Complete and submit initial applications and amendments to internal Sponsor committee, REC and other organisations as required for the clinical trial.
To liaise with R&D, finance, radiology and other support departments in the set up of trials and assessment of capacity and capability within the Royal Marsden Hospital.
To liaise with sponsors and R&D regarding clinical trial contracts.

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To liaise with R&D to ensure appropriate material transfer arrangements are in place for trials involving transfer or receipt of tissue.
Ensure that the Trial Master File (TMF) and Investigator Site Files (ISF) are correctly set-up and maintained.
Responsible for essential trial documentation including training and delegation logs.
Responsible for design, development and maintenance of Source Data Worksheets for collection of data.
Trial Conduct and Service Delivery
Initiate and manage day to day running of allocated trial(s) in accordance with Good Clinical Practice (GCP) and The Royal Marsden (RM) and Institute of Cancer Research (ICR) Standard Operating Procedures (SOPs).
The management of essential trial documentation (site file management, amendment documentation, capacity and capability review etc).
Ensure trial specific responsibilities delegated by the Sponsor to the Chief Investigator (CI) / Principal Investigator (PI) are carried out in accordance with contract.
Prepare and submit amendments to R&D.
Collaborate with clinical staff for reporting and updating Serious Adverse Events (SAEs).
Ensure timely raising of invoices for externally funded clinical trials.
Assist Sponsor and research team with provision of information such as accrual figures, recruitment statistics and data query resolution rates when requested.
Assist with data entry and query resolution when applicable.
Liaise with the allocated Data Manager to ensure that Case Report Form completion and query resolution meets sponsor deadlines and is of the required quality
Update of Central Portfolio Management System where required
Attend outpatient clinics, where appropriate, to support the smooth running of the clinics.
Trial Closure
To ensure trial closure is notified to R&D and appropriate regulatory bodies.
Assist in conducting the Trial Close Out visit and associated tasks.
To ensure appropriate archiving of trial documentation.
Communication and Networking
Act as a main point of contact for trial sponsors, the research team and participating sites in multi-centre studies
Communicate with staff at all levels, both internal and external relating to trial activities, regarding information

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which may be confidential and sensitive in nature.
To communicate effectively with other members of the research team, and external staff.
Unit Responsibilities:
To ensure that the trial is run in accordance with the protocol, sponsor guidelines, RM SOP's, the EU Directive 2001/20/EC and the GCP Directive 2005/28/EC.
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
Review all protocol amendments and implement any resulting changes in study procedures
Responsible for maintaining the Investigator Trial Files as required by the sponsor and according to GCP
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
Completing Data Validation spreadsheet, ensuring that all patient visits and assessments are tracked for invoicing purposes.
To ensure that all new members of the Research Team receive an Induction Pack which is updated regularly.
To ensure that new members of staff have read and understood the training material and that this is documented in a Training Record Form and the training records are filed in the department training file.
To ensure CV's for all members of staff are filed in the department training file and that these are signed and updated at least annually.
To ensure that all study personnel have up to date GCP training and that the certificate of training is filed in the department training file.
To ensure laboratory reference values are updated annually.
Maintaining and updating the Archive database and responsible for archiving 'closed studies' in collaboration with the Trial Coordinators and maintaining a record of details of archived essential documents (including details of the clinical research, archiving location, the date they were archived and the date to be destroyed, if available).
Attend regular departmental trial meetings with responsibility for taking and distributing minutes if required.
To ensure that all new and updated SOPs are distributed to members of the research team.

Confidentiality

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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.

General

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.
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 procedures.
Adhere to the regulatory rules and safety regulations of the Institute of Cancer Research and Royal Marsden Hospital.
Assist with the preparation of research papers as requested, and/or the collection of data required for publication/presentation of material.
Work in a flexible manner and be organised, meeting objectives and deadlines.
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.
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

Life Sciences or nursing degree (or equivalent)	Essential
Comprehensive knowledge of clinical research including GCP (EU Directive 2001/20/EC and GCP Directive 2005/28/EC) and Research Governance	Essential
A good understanding of the clinical trial process	Essential
Knowledge of the specific requirements of phase 2-4 oncology/radiotherapy studies	Desirable

Skills

Good time management skills and ability to prioritise effectively	Essential
Effective verbal and written communication skills	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
Ability to maintain adherence to written procedures	Essential
A methodical approach and attention to detail	Essential
Highly organised, ability to adapt to a dynamic clinical environment	Essential
Ability to influence and motivate at all levels	Desirable

Experience

12-18 months experience of working in oncology clinical trials	Essential
Experience of working in accordance with ICH-GCP regulatory standards for the conduct of clinical trials and UK Research Governance	Essential
Previous experience of radiotherapy treatment or radiotherapy research protocols	Desirable
Experience of working at an Investigator Site	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

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.