ICR The Institute of Cancer Research

Senior / Trial Manager
Candidate Information

July 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 Clinical Trials and Statistics Unit (CTSU)

The ICR-CTSU is an internationally recognised cancer clinical trials unit (CTU), led by Professor Bliss, with over 30 years' experience in the design, conduct and analysis of cancer clinical trials. ICR-CTSU receives programmatic core funding from Cancer Research UK (CRUK), is a UK Clinical Research Collaborative registered CTU and is one of fifteen CTUs recognised by the UK National Cancer Research Institute for a professional specialism in the development and delivery of cancer trials.

ICR-CTSU's strategic vision is to enact pull-through of world-leading science from ICR and elsewhere into patient benefit via high quality and efficient cutting-edge trials of smarter, kinder treatments which will ultimately translate into patient benefit internationally. Our main interests and areas of expertise are the evaluation of new drug treatments and technologies (including radiotherapy) and the use of biomarker-driven designs to clinically qualify putative predictive biomarkers and evaluate targeted treatments. Our portfolio includes innovative, efficient and adaptive trial platforms and early phase trials. We have a large network of collaborations within the clinical and academic community and with the pharmaceutical industry.

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Our portfolio of national and international phase II and III trials prioritises activity in three clinical and therapeutic domains:

- Breast and rare cancers trials
- Radiotherapy, urology and head and neck cancer trials
- Early phase and adaptive trial designs

These priority areas are supported by a cross-cutting biomarker and genomic analysis theme. This theme facilitates interrogation of the wealth of emerging trial data and focuses on the integration and translation of novel diagnostic, prognostic and therapeutic strategies into clinically relevant biomarker driven trial designs. We also manage an expanding number of early phase I/II cancer trials in collaboration with the Drug Development Unit, a joint unit of ICR and The Royal Marsden NHS Foundation Trust and a leading phase I unit globally.

Some highlights which demonstrate the breadth and impact of our portfolio include: In women with advanced triple negative breast cancer our TNT trial has demonstrated that those with an inherited BRCA mutation were twice as likely to benefit from carboplatin as the current standard of care (Nat Med. 2018 May;24(5):628-637) and is set to change practice internationally. Our TOPARP study led to FDA Breakthrough Designation of olaparib for advanced prostate cancers with BRCA and other DNA repair defects and has catalysed development of molecularly stratified treatment strategies for prostate cancer (N Engl J Med 2015; 373(18) 1697-708; ASCO 2019). The FAST-FORWARD trial provides evidence that a one-week course of radiotherapy in fewer but larger daily doses is as safe as the standard three-week therapy for women following surgery for early stage breast cancer (Lancet 2020 395(10237): 1613-1626) and is the most recent of our long-standing portfolio of phase III radiotherapy trials to report practice changing results.

We are a multi-disciplinary CTU, with more than 90 staff including statisticians/trial methodologists, clinical trials programme managers, trial managers, data managers, research IT programmers and administrative support staff. We have over 75 multi-centre trials on our portfolio which are in set up, open to recruitment, or in active or long-term follow-up, with access to further closed trials. Our senior management team hold leadership roles shaping clinical research at the local, national and international level.

Further information is available at:

ICR www.icr.ac.uk | **Twitter** @ICR_London | **Facebook** www.facebook.com/theinstituteofcancerresearch

ICR-CTSU

https://www.icr.ac.uk/our-research/centres-and-collaborations/centres-at-the-icr/clinical-trials-and-statistics-unit
Twitter @ICR_CTSU

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:	Division of Clinical Studies, ICR-CTSU
Pay grade / staff group:	Scientific Professional 5/ Scientific Professional 4
Hours / duration:	Full time (35 hours per week), Monday to Friday. Fixed term contract for 2 years
Reports to:	Clinical Trials Programme Manager
Line Management:	Data Managers/Trial Administrators
Main purpose of the job:	The successful applicant will work with Clinical Trials Programme Managers, Statisticians, Data Managers and Administrators and will be responsible for the day to day management of the trial(s) through set-up, recruitment and reporting and the co-ordination of data management and biological sample collection activities. Senior roles will lead on trial development and set up activities, and provide Clinical Trial Programme Manager level oversight for trials in follow up.

Role Summary:

The Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU) runs a diverse portfolio of national and international phase III multi-centre randomised controlled trials, and phase II targeted treatment trials, with a special emphasis in breast, urological, lung and head and neck cancer treatments. To reflect the ongoing expansion and diversification of our trials portfolio, we require a Senior / Trial Manager to provide support for Clinical Trial Programme Managers working on a variety of cancer clinical trials within the Unit. The job is varied and will give the post holder valuable experience in many aspects of clinical trial methodology and organisation. The responsibilities of the post include managing the day to day running of the trial(s) through set-up, recruitment and reporting, promoting the trial(s) to ensure successful recruitment, overseeing data management activities, and co-ordinating and managing biological sample collection from participating centres. Senior roles will lead on trial set up activities, support and mentor less experienced trial managers, and provide Clinical Trial Programme Manager level oversight for trials in follow up.

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Duties and responsibilities:

Trial initiation

Prepare trial documentation e.g. protocols, trial guidance notes, risk assessments, electronic case report forms (eCRFs), and patient information sheets under the guidance of the CTPM and in collaboration with relevant members of the Trial Management Group (TMG) including the Chief Investigator (CI) and ICR-CTSU Scientific Lead.
Prepare regulatory, ethics and HRA submissions, under the guidance of the CTPM, and in collaboration with relevant members of the TMG.
Ensure the required approvals and agreements are in place before the trial opens to recruitment.
Set up trial specific procedures within ICR-CTSU in accordance with ICR-CTSU SOPs to ensure the efficient management of the trial.
Oversee the design and validation of the clinical study database and registration/randomisation system in liaison with Trial Statistician, IT Programmer, CTPM and Data Managers.
Contribute to the successful launch of the trial including presentation at launch meetings.
Plan and perform site initiation training via teleconference or face-to-face visits ensuring sites have all applicable documentation in place and that principal investigators and site staff understand the protocol and their responsibilities within the trial.
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Trial management

Oversee the day-to-day conduct of the trial at participating sites, providing support and advice and addressing any logistical issues as they arise.
Liaise closely with the CI, ICR-CTSU Scientific Lead, CTPM, Statistician and other key members of the TMG to ensure on-going clinical, scientific and operational oversight.

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Chair and lead internal trial team meetings.
Act as the principal point of contact for participating sites, sponsor(s), funder(s), pharmaceutical partners, regulatory authorities and the trial oversight committees.
Organise regular meetings of the TMG, preparing the agenda and meeting papers, presenting updates during the meeting and producing minutes following the meeting in a timely manner.
Organise and attend meetings of the trial oversight committees, preparing the agenda and meeting papers, and taking minutes as required.
Coordinate any trial-related biological sample collections and liaise closely with central laboratory teams.
Develop monitoring plan and perform on-site monitoring visits to participating sites as required, to verify trial activities are compliant with the trial protocol, GCP and all applicable regulations.
Ensure trial recruitment and retention are monitored and establish procedures for dealing with problems arising from any shortfall in collaboration with relevant members of the TMG.
Update trial documentation as necessary e.g. protocols, trial guidance notes, case report forms (CRFs) and patient information sheets.
Prepare and submit amendments to the REC approval/CTA under the guidance of the CTPM, and in collaboration with relevant members of the TMG.
Draft regular progress and safety reports e.g. to funding bodies, TMG, Trial Steering Committee, REC, MHRA.
Contribute to the preparation of abstracts, posters and manuscripts.
Maintain quality control procedures for all aspects of trial conduct to ensure compliance with the principles of Good Clinical Practice, research governance standards and all applicable legislation (e.g. The Medicines for Human Use (Clinical Trials) Regulations, General Data Protection Regulation, Good Clinical Laboratory Practice, Human Tissue Act/Human Tissue Bill (Scotland)).
Maintain the Trial Master File to ensure a clear audit trail of trial activities is retained.
Facilitate any audit, inspection or progress visit processes required by regulatory bodies, or sponsor(s).

Trial Promotion

Liaise with participating sites and potential collaborators to promote trial recruitment.
Draft and circulate regular newsletters.
Plan, organise and give presentations at meetings of investigators/research nurses/trial coordinators as appropriate.
Promote the trial at national scientific meetings developing presentation materials (slides/posters/flyers) as required.

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Data Management

Develop the data management plan in liaison with the Trial Statistician, Data Managers and CTPM and implement and oversee timely and efficient procedures for the collection, entry and verification of all patient data.
Maintain record management systems for all trial material.
Liaise with site staff to ensure trial procedures are being followed to promote the reporting of high quality data.
Prepare data for interim and/or full analysis in collaboration with the trial Data Managers and Statistician.

Biological sample management

Develop procedures for biological sample management (collection, tracking and shipment) in collaboration with the central laboratory.
Develop procedures for biological sample reconciliation in liaison with the Data Managers and central laboratory team, under the guidance of the CTPM.

Staff Management

Supervise members of the in-house trial team, e.g. Data Managers and Administrators, providing guidance, training and advice as required.
Prioritise and allocate workloads within the trial team to ensure the trial is supported effectively and efficiently.
Line manage members of the in-house trial team, where required, conducting annual appraisals to set objectives, review progress against objectives and identify areas for development.

New research initiatives

Support the preparation of funding applications for new study proposals.
Assist senior staff with site feasibility assessment for new studies.

General duties

Participate in the rota for the ICR-CTSU randomisation service. The randomisation service is manned 9am-5pm each working day.
Attend and contribute to ICR-CTSU's monthly research meetings, departmental meetings and Trial Manager meetings.
Support and participate in departmental working groups.

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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

Senior Trial Manager Responsibilities

Lead on trial set up activities
Support less experienced Trial Managers on specific trials
Provide training and mentorship to less experienced Trial Managers
Provide Clinical Trial Programme Manager level oversight for trials in follow up

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In general ICR-CTSU staff work from 9 am to 5 pm with a one hour lunch break. However, the post holder may be required to work outside these hours to meet deadlines and to attend on-site monitoring visits. It may also be necessary for the post holder to be available for occasional evening meetings and for meetings and monitoring visits to include overnight stops.

This role would usually be office based however, we currently have a blended approach to home and office working, and flexible working options may be considered.

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.

In addition, there will be other duties consistent with the nature and grade of the post.

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Person specification

Education and Knowledge

First degree or equivalent level qualification in biological science, social science or other relevant subject (including nursing and health care disciplines).	Essential
A sound understanding of the principles of Good Clinical Practice, Data Protection, the EU Clinical Trials Directive and research governance.	Essential
A good understanding of medical terminology and clinical trial design	Essential
Excellent knowledge of PC based Windows and Microsoft Office software.	Essential
An understanding of cancer and its treatment modalities	Desirable
For Senior Trial Managers (as above plus)	
Expert knowledge of trial management systems and processes	Essential

Skills

Ability to work accurately, with a strong attention to detail	Essential
Excellent organisational and time management skills	Essential
Excellent oral and written communication skills	Essential
Ability to maintain adherence to written procedure and clinical and regulatory standards applicable to ICR-CTSU clinical trials	Essential
Excellent interpersonal skills	Essential
Ability to use initiative and think logically or laterally to resolve problems	Essential
Ability to lead and motivate a team	Desirable
For Senior Trial Managers (as above plus)	
Ability to mentor and train less experienced staff	Essential
Ability to prioritise own work	Essential
Ability to work with minimal supervision	Essential

Experience

Experience in study coordination	Essential

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Experience of working to deadlines and organising own workload	Essential
Experience of data management	Essential
Experience of the central coordination of multi-centre clinical trials	Desirable
Experience of clinical trial monitoring	Desirable
Experience of pharmacovigilance management and reporting	Desirable
General administrative experience	Desirable
Experience of clinical trial reporting to stakeholders (e.g. oversight committees, funders, regulatory, ethics)	Desirable
Experience of giving oral presentations	Desirable
Experience of working on studies involving collection of biological samples	Desirable
Experience of handling large data sets	Desirable
Line management experience	Desirable
For Senior Trial Manager (as above but experience listed as desirable is essential)	

General

Flexible and adaptable approach to managing workload	Essential
Willing to travel on occasion	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

You may contact the ICR-CTSU for further information by emailing ctsu@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.