ICR The Institute of Cancer Research

Clinical Trials Programme 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 Judith 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, 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 that 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

Clinical Trials Programme Manager
Candidate Information

platforms and early phase trials. We have a large network of collaborations within the clinical and academic community and with the pharmaceutical industry.

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, which comprises 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.

Clinical Trials Programme 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 Trials Programme Manager
Candidate Information

Job description

Department / division:	ICR-CTSU, Division of Clinical Studies
Pay grade / staff group:	Scientific Professional 3
Hours / duration:	Full time (35 hours per week), Monday to Friday. Fixed term contract for 2 years
Reports to:	ICR-CTSU Director/Deputy Director
Line management:	Trial Managers/Data Managers/Trial Administrators
Main purpose of the job:	To provide strategic oversight to a defined programme of research within the ICR-CTSU portfolio, playing a key role in the development and initiation of new trials and providing operational oversight of dedicated trials teams to ensure successful trial delivery.

Role Summary:

All ICR-CTSU trials fall under the scientific and methodological leadership of a member of ICR Faculty. Clinical Trials Programme Managers (CTPMs), working under the direction of the scientific lead and Operations Director, are each responsible for overseeing a component of the trials portfolio, ensuring trials are initiated and delivered effectively. In addition to dedicated statistical and IT support, each trial has a trial team comprising of trial management, data management and administrative support. The CTPM is responsible for the development and initiation of new trials and for overseeing the trial team, ensuring staff are suitably trained and supported. In addition, CTPMs are expected to provide scientific or operational expertise and leadership within a defined area of research or trial conduct.

Duties and responsibilities:

Development and set up of new studies/sub studies in the context of relevant local, national and international priorities and ongoing research interests.

Developing successful funding applications; contributing to the scientific, financial and trial management aspects of the application
Ensuring effective and timely site feasibility assessments
Developing study protocols and patient information material, ensuring compliance with the highest scientific, regulatory and ethical standards
Ensuring appropriate sponsorship arrangements are in place for the conduct of the study
Liaising with the ICR contracts managers, sponsor organisations, key collaborators and pharmaceutical partners to ensure appropriate contractual arrangements for trial conduct are in place

Clinical Trials Programme Manager
Candidate Information

Negotiating with external collaborators, including pharmaceutical partners, to ensure effective provision of protocol treatments
Obtaining regulatory, ethics and HRA approvals for trial conduct
Ensuring successful launch of new trials, including presentations at investigator meetings, in conjunction with the Chief Investigator (CI) and the trial manager

Overseeing the conduct of a number of studies within the ICR-CTSU portfolio to ensure their smooth running and progress

Working closely with ICR-CTSU scientific leads, CIs, trial oversight committees, sponsor organisations and study teams to ensure effective communication between all parties
Overseeing trial team, ensuring appropriate arrangements are in place for the delivery and management of study treatment and the collection of high quality data and biological specimens
Continually reviewing milestones and timelines to ensure effective conduct and timely reporting across the studies, including annual progress and safety reporting to regulators and ethics committees
Producing and/or reviewing reports to funders and other key organisations, e.g. Cancer Research UK, National Institute for Health Research, National Cancer Research Institute
Producing and/or reviewing reports to trial oversight committees, including the Trial Management Group, Trial Steering Committee and, if required, the Independent Data Monitoring Committee and attending meetings of those committees as necessary

Contributing to ICR-CTSU's scientific output

Providing oversight of key aspects of research within the post-holder's trials portfolio
Identifying and conducting additional research which supports ongoing and/or proposed trials
Drafting clinical trial and methodology abstracts and publications in conjunction with CIs, trial managers and statisticians, as required

Line management of a team of trial staff within the agreed portfolio

Leading, motivating and developing staff within the team
Prioritising and allocating workloads within the team to ensure effective delivery of the portfolio
Identifying the training requirements of the team to ensure operational objectives and, where appropriate, personal development goals are met
Providing and/or co-ordinating training and support where required
Conducting annual appraisals to review progress, set objectives and identify areas for development

Dealing with any staffing issues that may arise through the application of ICR performance management procedures

Contributing to the ICR-CTSU Quality Management System (QMS)

Assisting with the preparation and conduct for any GCP inspection or 3rd party audit within ICR-CTSU
Contributing to the review of ICR-CTSU systems and processes to ensure continued compliance with relevant legislation
Contributing to Quality Assurance Review Team meetings or other working groups to facilitate implementation of the QMS across the trial portfolio
Advising and supporting staff on the ethical principles, research governance and regulatory standards for the conduct of clinical trials
Assisting with the audit of trials activity within the Unit

Proactive Member of ICR-CTSU's Management Group

Attending and contributing to regular management and operational meetings with other senior staff
Contributing to regular team meetings and providing feedback at those meetings on behalf of the Management Group
Leading and promoting new initiatives within ICR-CTSU
Assisting with the preparation for the Cancer Research UK quinquennial reviews, working with other senior staff and delegating tasks as necessary
Undertaking occasional teaching sessions and formal presentations both within ICR and externally
Developing links with external national bodies and trial related groups

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
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

Clinical Trials Programme Manager
Candidate Information

Person specification

Education and Knowledge

Minimum of a first degree or equivalent qualification in biomedical sciences or an allied subject (including health care disciplines)	Essential
Postgraduate qualification in biomedical sciences or an allied subject	Desirable

Skills

Proven interpersonal and communication skills to: • work as a team player and foster a team environment; • communicate effectively with internal colleagues and external collaborators; • manage staff	Essential
Good IT skills	Essential
Excellent presentation skills	Essential
Excellent organisational and time management skills to manage and deliver a range of tasks and projects to tight deadlines	Essential
Ability to work with others within a multidisciplinary team and to work independently	Essential
Ability to project a positive and professional image of ICR-CTSU to stakeholders from the UK and overseas	Essential
Ability to make effective and enthusiastic contributions to scientific and management meetings	Essential
Ability to work with clinical and management colleagues at all levels across a range of organisations	Essential
Ability to chair meetings effectively	Desirable
Highly motivated with the ability to influence and inspire others	Essential
Effective decision maker	Essential
Ability to work effectively under direction and on own initiative	Essential
Strong attention to detail	Essential
Interest in developing research proposals that are compatible with ICR-CTSU's overall scientific strategy	Essential

Clinical Trials Programme Manager
Candidate Information

Flexible and innovative approach to working, including problem solving through lateral thought, management of change and a desire to develop knowledge	Essential

Experience

Proven track record working at a senior level (i.e. management team or equivalent) within a research oriented group	Essential
Experience of managing, directing and supporting staff	Essential
Proven project management/central coordination experience gained in the phase II or III multi-centre trial setting	Essential
Experience/knowledge of the current UK ethics and regulatory processes associated with clinical research	Essential
Excellent knowledge of the EU Clinical Trials Directive, UK Clinical Trials Regulations, Principles of Good Clinical Practice and research governance framework legislation together with the ability to disseminate the knowledge and information	Essential
Experience of scientific and logistical input into trial documentation including protocol, CRFs, manuscripts and reports	Essential
Experience of biomarker driven research	Desirable
Experience/knowledge of laboratory quality systems and procedures	Desirable
Experience of working in an academic research environment	Desirable
Experience of working in oncology or related fields (i.e. radiotherapy)	Desirable
Experience of developing/managing quality assurance documentation and systems	Desirable
Experience of successful grant submissions	Desirable
Experience of preparing for regulatory/sponsor inspection	Desirable
Experience of negotiations with external organisations such as funding bodies, Chief Investigators, sponsors, pharmaceutical companies	Desirable
Up to date knowledge of current data and views of experts in relevant fields e.g. National Cancer Research Institute Clinical Studies Groups, Cochrane Collaboration	Desirable
Experience of scientific report writing (e.g. clinical study report, peer reviewed publication)	Desirable
Experience of preparing and delivering complex presentations and reports at national/international meetings	Desirable

General

Availability and willingness to travel (on occasion)	Essential

Clinical Trials Programme 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

You may contact 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.