ICR The Institute of Cancer Research

Trial Manager (Maternity Cover)

Candidate Information

April 2025

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. 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 are consistently in the top performing universities in the league table of university research quality compiled from the Research Excellence Framework (REF 2014 & 2021). 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 (ICR-CTSU)

Under the Directorship of Professor Emma Hall, the ICR-CTSU is an internationally recognised, methodologist-led academic clinical trials unit (CTU), 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 and is a UK Clinical Research Collaborative Registered CTU.

ICR-CTSU translates cutting-edge science into quality clinical trials that can transform cancer care, by:

- Leading patient-centred trials of smarter, kinder therapies that treat cancer more precisely
- Transforming how we design and conduct trials with innovations in trial methodology
- Learning as much as we can with integrated translational research and data science
- Championing purposeful and inclusive patient and public involvement
- Embedding research to improve the sustainability of our trials
- Supporting interdisciplinary training to empower the next generation of trialists

Trial Manager (Maternity Cover)
Candidate Information

ICR-CTSU's portfolio of national and international phase II and III trials covers a wide range of disease sites from common cancers (e.g. breast, prostate, lung) through to rarer malignancies (e.g. ovarian, testicular, penile). Our expertise in intervention assessment includes novel targeted drugs and immunotherapy, hormonal therapies and chemotherapy, radiotherapy (including advanced targeted technologies), drug-drug and drug-radiotherapy combinations, imaging technologies and diagnostics/companion diagnostics. Our cross-cutting Integrative Genomic Analysis team facilitates interrogation of the wealth of emerging trial data to further understand mechanisms of action and markers of treatment sensitivity or resistance and to translate novel diagnostic, prognostic and therapeutic strategies into clinically relevant biomarker-driven trial designs. Our Early Phase and Adaptive Trials team provide methodology leadership to an expanding number of early phase trials.

Recent publications highlighting the breadth and impact of our portfolio include:

- PACE: radiotherapy in five larger daily doses is as good as the standard 4-week therapy for patients with low/favourable intermediate risk prostate cancer (New Engl J Med 2024); the most recent of our long-standing portfolio of phase III radiotherapy trials to report practice changing results.
- plasmaMATCH: pioneering evidence to support the use of liquid biopsy ctDNA mutation detection to inform targeted treatment selection for breast cancer patients thus avoiding the need for invasive tumour biopsies (Lancet Oncol 2020).
- POUT: adjuvant chemotherapy improves outcomes for patients with upper tract urothelial cancer (J Clin Oncol 2024)
- NICAM: a phase II study demonstrating activity of nilotinib in a rare form of melanoma with a mutation in the *KIT* gene (Cell Rep Med 2024).

Our methodology work includes the DEFINE study - SPIRIT and CONSORT extensions for early phase dose-finding trials – to enhance transparency and reproducibility for trial protocols and reports (BMJ 2023; BMJ 2023), a review of clinical trial designs for evaluating and exploiting cancer evolution (Canc Treat Rev 2023) and use of routine collected data as an alternative to hospital based follow-up (preprint).

We are a multi-disciplinary CTU, with more than 90 staff including statisticians/methodologists, clinical trial programme management, trial management, data management, research IT programming and administrative support staff. We are based at ICR's Sutton site.

We have over 75 multi-centre trials in set up, open to recruitment, or in active or long-term follow-up. 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 | **Facebook** www.facebook.com/theinstituteofcancerresearch

ICR-CTSU www.icr.ac.uk/research-and-discoveries/centres-and-strategic-collaborations/clinical-trials-and-statistics-unit-icr-ctsu | **Bluesky** @icr-ctsu.bsky.social

Trial Manager (Maternity Cover)
Clinical Trials and Statistics Unit

Candidate Information

Job Description

Department / division:	Clinical Trials and Statistics Unit (ICR-CTSU), Division of Clinical Studies
Pay grade / staff group:	Scientific Professional 5
Hours / duration:	Part time (0.6FTE). Fixed term contract for up to 1 year.
Reports to:	Clinical Trials Programme Manager
Main purpose of the job:	To work as part of a multidisciplinary team to manage the day to day running of trials through set-up, recruitment and reporting.

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 Trial Manager to provide support for Clinical Trial Programme Managers working on a variety of cancer clinical trials within the Unit.

Duties and responsibilities:

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.

Trial Manager (Maternity Cover)
Clinical Trials and Statistics Unit

Candidate Information

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.

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.
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.

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.

Trial Manager (Maternity Cover)
Clinical Trials and Statistics Unit

Candidate Information

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.

General CTSU 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.
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.

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

Trial Manager (Maternity Cover)
Clinical Trials and Statistics Unit

Candidate Information

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 developments

Trial Manager (Maternity Cover)
Clinical Trials and Statistics Unit

Candidate Information

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) or equivalent, relevant work experience.	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

Skills and qualities

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

Experience

Experience in study coordination	Essential
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
Experience in study coordination	Essential

General

Ability to work independently and as part of a team	Essential
Ability to project a positive and professional image of the ICR-CTSU to both ICR and external collaborators	Essential
Ability to maintain adherence to written procedures and clinical and regulatory standards applicable to ICR-CTSU clinical trials	Essential
Flexible and adaptable approach to managing workload	Essential
Willing to travel on occasion	Essential

Trial Manager (Maternity Cover)
Clinical Trials and Statistics Unit
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

Trial Manager (Maternity Cover)
Clinical Trials and Statistics Unit
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. All positions at ICR-CTSU are eligible for discretionary hybrid working. 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

For general queries about the recruitment process, please contact ICR-CTSU, email: ctsu@icr.ac.uk.

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