ICR The Institute of Cancer Research

Trials Methodologist/Senior Trials Methodologist

Candidate Information

March 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

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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

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Job Description

Department / division:	Clinical Trials and Statistics Unit (ICR-CTSU), Division of Clinical Studies
Pay grade / staff group:	Research Training Fellow 2
Hours / duration:	Full time (35 hours per week), Monday to Friday. Fixed term contract for 2 years in the first instance. Part time working (minimum 60% FTE) will be considered. This post is eligible for discretionary hybrid working.
Reports to:	ICR-CTSU Scientific/Methodology Lead or Principal/Lead Statistician
Main purpose of the job:	To work as part of a multidisciplinary team on trials methodology research, as well as the statistical development, oversight and analysis of a number of clinical trials within ICR-CTSU's portfolio and the early phase portfolio in collaboration with the Drug Development Unit and external organisations.

Role Summary:

The post-holder will have a dual role: (a) developing novel methodologies in the design and analysis of clinical trials, and (b) applying efficient methods in new and ongoing trials. They will work as part of a multi-disciplinary team on trials methodology research, as well as the statistical development, oversight and analysis of a number of clinical trials within ICR-CTSU's portfolio and the early phase portfolio in collaboration with the Drug Development Unit and external organisations.

We seek an experienced and highly motivated statistician with an interest in researching new statistical methods to improve efficiency in clinical trials and who is looking for opportunities to apply their statistical knowledge across various therapeutic areas in oncology. Effective oral and written communication skills, along with enthusiasm for collaborating with others from different disciplines, are essential.

Duties and responsibilities:

The post-holder will be a key academic staff member of the statistical team at ICR-CTSU. They will work with independence under the guidance of the ICR- CTSU Scientific/Methodology Lead for Early Phase and Adaptive Trials, Professor Christina Yap. The main focus is to develop and implement efficient trial methodology in oncology clinical trials across all trial phases; with a specific emphasis in early phase and adaptive trials. The post-holder will be supported in their career development through a range of formal courses and on-the-job training. Specific duties and responsibilities will include some or all of the following either directly or supervised by a principal statistician or Group Leader:

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Duties and responsibilities

Trials Methodology Research

Undertake methodology research aimed at improving the efficiency of clinical trials across all phases, motivated by real-life oncology trials
Work closely in partnership with clinical investigators and the trial team to implement efficient methodology in the design, conduct, analysis and reporting of clinical trials
Contribute to determining the direction of the research within their designated area of specialism, under the overall leadership of the ICR-CTSU Scientific/Methodology for Early Phase and Adaptive Trials
Contribute (as a co-applicant) to funding applications for trials methodology project grants or clinical trials
Work with limited supervision to identify, develop, modify, and apply the necessary techniques to achieve the research objectives
Write high-quality peer-reviewed trials methodology publications and present at national and international conferences
Carry out necessary administrative and managerial tasks appropriate to the level of appointment, in support of research projects within the team; these tasks will include organisation of project meetings and documentation
Contribute to organising webinars, seminars, workshops, and conferences
Assist with the training and supervision of research students, trialists and others, who may be working in related research

Initiation and Design of Clinical Trials

Provide high quality statistical input in design of clinical trials
Contribute to development and defining of the study question; this will often include a review of the available literature and analysis of data available from other sources
Develop the study protocol with Protocol Development Group, particularly the statistical considerations of sample size and analysis strategy
Contribute to the design of (electronic-) Case Report Forms and trial databases to ensure data are collected and stored to meet the requirements of statistical monitoring and analysis, and in line with relevant guidelines and legislation (e.g. Data Protection Act, Research Governance Framework, ICH Statistical Principles for Clinical Trials, Good Clinical Practice)
Support IT programming/database staff to set-up, test and maintain trial databases (including randomisation systems)

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Analysis and Management of Clinical Trials

Review and/or develop statistical analysis plans ensuring compliance with relevant guidelines
With trial managers, model recruitment predictions, providing advice to the Trial Management Group for proactive intervention where necessary
Assist and advise the trial team to ensure completeness and correctness of data during both recruitment and follow-up phases of trials
Undertake central statistical monitoring of data to assist audit and quality control
Assist the trial team in the preparation of data for regular safety reporting to the competent authority, ethics committees and Sponsor
Assist the trial team in the preparation of reports for Trial Management Group and Trial Steering Committee meetings, especially in the specific methodological aspects of the trial
Undertake interim analysis and produce reports for submission to the Independent Data Monitoring Committee meetings, or provide support to the trial statistician in specific methodological aspects of the trial
Undertake or support final analyses and compilation of reports for presentation and publication
Undertake additional analyses, exploring novel methodologies as required, and support the trial statistician in the final analyses and compilation of reports for presentation and publication
Work with statistical colleagues to develop or modify novel statistical methodology as required by each analysis (e.g. modelling of biological data, including some genetic/genomic data). This may include collaboration with others with similar interests (e.g. through the MRC-NIHR Trials Methodology Research Partnership or the UKCRC Registered Clinical Trials Units) to develop professional specialism
Liaise and work with clinical investigators, bioinformaticians and translational analysts to understand the biological background for each analysis and apply or modify the appropriate statistical methodology (e.g. modelling of clinical outcome data integrating complex biological data structures)
Keep up to date with the related medical and statistical literature
Contribute to manuscript writing of clinical trial results

Other duties

Contribute to ICR scientific output by drafting clinical trial and methodology abstracts and papers in conjunction with ICR-CTSU Methodology Leads, trial team and external chief investigators
Promote the work of ICR-CTSU by presenting methodology output at national/international symposia
With statistical colleagues, provide monthly review of research projects submitted to the ICR/Royal Marsden Hospital Committee for Clinical Research; this includes review of sample size calculations and statistical methodology
Contribute to review and development of relevant standard operating procedures to promote best practice
Be familiar with trials randomised via ICR-CTSU in order to provide a competent randomisation service
Contribute to meetings of ICR-CTSU statisticians, joint meetings of ICR-CTSU and Royal Marsden based statisticians and other relevant team research meetings
Provide occasional consulting advice to clinical and scientific colleagues and occasional teaching lectures to ICR-CTSU staff, ICR students and other undergraduate/postgraduate medical and nursing courses run locally

Attend statistical and clinical meetings both locally and externally, as appropriate
Adhere to relevant standard operating procedures and work within the guidelines laid out by the ICR-CTSU Quality Management System
Contribute to relevant ICR committees as required
Contribute to wider clinical trials national “citizenship” e.g. through membership of Data Monitoring Committees, Trial Steering Committees and/or peer reviewing

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
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

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Person specification

Education and Knowledge

MSc in medical statistics/biostatistics or an allied field (e.g. public health, epidemiology, data science) with relevant work experience OR PhD in medical statistics/biostatistics or an allied field	Essential
A sound understanding of the concept of all phases of clinical trials	Essential
A good grasp of the scientific background to clinical trials	Essential
A good understanding of cancer and its treatment modalities	Desirable
Knowledge of Good Clinical Practice, the EU Clinical Trials Directive, Research Governance Framework, ICH Statistical Principles for Clinical Trials	Desirable

Skills and qualities

A desire to develop and apply existing and novel statistical methods to the requirements of a diverse range of statistical problems	Essential
Extensive experience with the statistical programming language of R or STATA	Essential
Excellent knowledge of PC based Windows and Microsoft Office software	Essential
Excellent written and spoken English	Essential
Effective oral and written communication skills; the post holder will be required to communicate statistical concepts and the scientific rationale for clinical trials to clinicians and other health care professionals	Essential
Excellent organisational and time management skills; ability to work to deadlines and organise and prioritise both personal and project workload	Essential
Ability to work accurately, with a strong attention to detail	Essential
Excellent interpersonal skills to facilitate liaison with colleagues and collaborators	Essential

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Experience

Experience in presenting scientific work, both written and oral	Essential
Demonstrable ability to publish, including the ability to produce high-quality academic writing	Essential
Applying statistical methods to real data	Essential
Performing literature reviews	Desirable
Statistical and critical review of documents	Desirable
Familiarity with clinical trials procedures	Desirable
Research experience in early phase and/or adaptive trials	Desirable
Research experience in Bayesian methods	Desirable
Trial methodology research in design, conduct, analysis or reporting of clinical trials	Essential
Sample size calculations	Essential
Designing clinical studies	Desirable
Statistical consulting	Desirable
Survival analysis methods	Desirable
Analysing longitudinal data sets	Desirable
Experience in line management, supervising or mentoring	Desirable
Working as an applied medical statistician within academia or the pharmaceutical industry	Desirable
Experience in teaching or training statistical concepts to a non-statistical audience	Desirable

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
Experience of handling sensitive and confidential information	Desirable
Motivated to publish independent research	Desirable

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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

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.

This job description reflects the current position and is subject to review and alteration in detail and emphasis in the light of future changes or development.