



Data Manager 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

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ICR-CTSU is a key part of the ICR/Royal Marsden Centre for Trials and Population Data Science. The Centre brings together expertise across the two institutions to advance methods-based and methodologist-led research to improve cancer research outcomes and quality.

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 (<u>Lancet Oncol 2020</u>).
- POUT: adjuvant chemotherapy improves outcomes for patients with upper tract urothelial cancer (<u>J Clin Oncol 2024</u>)
- NICAM: a phase II study demonstrating activity of nilotinib in a rare form of melanoma with a mutation in the KIT gene (<u>Cell Rep Med 2024</u>).

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

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

 $\hline \textbf{ICR-CTSU} \ \underline{www.icr.ac.uk/research-and-discoveries/centres-and-strategic-collaborations/clinical-trials-and-statistics-unit-icr-ctsu \ | \ \underline{\textbf{Bluesky}} \ \underline{@icr-ctsu.bsky.social}$

Candidate Information

Job Description

Department / division: Clinical Trials and Statistics Unit (ICR-CTSU), Division of Clinical Studies

Pay grade / staff group: Scientific Professional 7

Hours / duration: Full time (35 hours per week), Monday to Friday. Fixed term contract for 2 years in the first instance.

Reports to: Clinical Trials Programme Manager/Trial Manager

Role Summary:

We require a Data Manager to provide support for Trial 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 the collection of high quality data and coordination of biological samples collection from multiple participating centres. Trials may use paper case report forms or electronic data capture to collect data from sites.

Duties and responsibilities:

The successful applicant will work with Trial Managers, Statisticians and Administrators and duties will include liaising with hospitals to collect patient data according to the protocol, overseeing biological sample collection at sites, reviewing and cleaning data submitted by sites and assisting with site monitoring visits. Specific duties and responsibilities will include some or all of the following:

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Duties and responsibilities

Management of data and biological sample

Design and validate the clinical study database and registration/randomisation system in liaison with the Statistician, IT Programmer, Trial Manager and Clinical Trials Programme Manager (including annotation of the CRF, development of the database and validation specifications and User acceptance testing)

Develop the Data Management Plan in liaison with the Statistician, Trial Manager and Clinical Trials Programme Manager

Enter and review clinical data on the clinical study databases

Specify, develop, validate and run reports in clinical review software (JReview®) in order to perform data checking and cleaning

Management of clinical database change requests in liaison with the Statistician, IT Programmer, Trial Manager and Clinical Trials Programme Manager

Perform central data cleaning, including raising data queries, and liaising with participating hospitals to resolve them

Chase outstanding data and biological samples from participating hospitals

Log and monitor return of case report forms (CRFs) and queries, escalating any issues as appropriate

Log, monitor and reconcile biological sample collection between participating hospitals and central laboratories

Produce summary reports to assist the Trial Manager and Statistician in oversight of trial data

Provide study-specific data management training for research teams at participating hospitals

Request screening log data from participating hospitals; enter and query as required

Administrative work

Set up and/or maintain record management systems for all trial material, including patient data and biological sample collections

Assist in preparation and/or maintaining up to date trial related documentation such as Trial Master and Site Investigator Files

Deal with telephone queries about the trial(s) as necessary

Assist in the preparation of reports and presentations for meetings

Assist in the preparation of abstracts and manuscripts

Take and draft minutes of meetings as required

Ensure that site contact details and circulation lists are kept up to date

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Other duties

Join the rota for the ICR-CTSU telephone randomisation service. The randomisation telephone line is staffed 9am-5pm each working day

Attend and contribute to team meetings (Unit and Trial level) and Trial Manager/Data Manager meetings

Contribute to departmental working groups e.g. the Data Management Working Group

Trial Management

Liaise closely with hospital personnel (i.e. clinicians, nurses, data managers) at participating centres to promote trial recruitment

Assist the Trial Manager with the planning and organisation of Trial Steering Committee and Trial Management Group meetings

Assist the Trial Manager in the preparation of progress reports (e.g. for regulatory and funding bodies and Trial Management Group) as required

Perform site monitoring visits at participating centres to verify study data and assess trial progress

Trial Promotion

Liaise closely with hospital personnel (i.e. clinicians, nurses, data managers) at participating centres to promote trial recruitment

Draft regular newsletters for circulating to trial participating sites which should include updated information on accrual and any other trial related issues

Assist in the planning and organisation of trial investigator meetings. This may entail selecting appropriate dates, venues, assisting with the drawing up of programmes, identifying and inviting appropriate delegates to attend, ensuring that accurate information is circulated to delegates, producing PowerPoint presentations and other meeting materials

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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

First degree or equivalent level qualification	Essential
First degree or equivalent level qualification in Biomedical Sciences or an allied subject (including nursing and health care disciplines)	Desirable

Skills and qualities

Excellent interpersonal skills to facilitate liaison with colleagues and trial collaborators	Essential
Effective oral and written communication skills – the post holder will be required to respond to queries from clinicians and nurses about clinical trials	Essential
Ability to work independently and as part of a team on several projects with enthusiasm and a professional attitude	Essential
Excellent organisational and time management skills	Essential
Ability to work accurately with attention to detail	Essential
Ability to draft routine correspondence (e.g. emails, letters and newsletters)	Essential
IT literacy, a good working knowledge of Microsoft Word and Excel and ability to access information from the internet	Essential
Ability to grasp scientific/medical concepts effectively and efficiently	Essential
Interested in learning about cancer and/or the conduct of clinical trials	Essential
An understanding of cancer and its treatment modalities	Desirable
An understanding of the concept of randomised clinical trials and phases of clinical trials	Desirable
An understanding of the principles of Good Clinical Practice, Data Protection, the EU Clinical Trials Directive and research governance	Desirable
Ability to maintain adherence to written procedures and clinical and regulatory standards applicable to clinical trials	Essential

Experience

Experience of managing data in hard copy and electronic form	Essential
Experience with clinical databases e.g. MACRO, RedCAP, RAVE, OCRDC	Desirable
Experience with clinical review software e.g. JReview®	Desirable
Experience in using Microsoft PowerPoint and Visio	Desirable
Experience of database specification and testing	Desirable
Experience of development or review and input to Data Management Plans	Desirable

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Experience of handling large sets of data	Desirable
Experience of working in oncology	Desirable

General

Flexible and adaptable approach to managing workload	Essential
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

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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

Data Manager

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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. 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.