ICR The Institute of Cancer Research

Job description

Data Manager

September 2024

Directorate:	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

The Clinical Trials and Statistics Unit (ICR-CTSU)

Under the co-directorship of Professors Judith Bliss and 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 UK Clinical Research Collaborative registered.

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 the way 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

Our mission is to make the discoveries that defeat cancer.

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. myeloma, ovarian, testicular, penile). 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, many run in collaboration with the Drug Development Unit, a globally leading joint unit of ICR and The Royal Marsden NHS Foundation Trust.

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. Some highlights which demonstrate the breadth and impact of our portfolio include: The FAST-FORWARD trial provides evidence that a 1-week course of radiotherapy in fewer but larger daily doses is as safe as the standard 3-week therapy for women following surgery for early stage breast cancer (Lancet 2020) and is the most recent of our long-standing portfolio of phase III radiotherapy trials to report practice changing results. Our plasmaMATCH breast cancer trial provides pioneering evidence to support the use of liquid biopsy ctDNA mutation detection to inform targeted treatment selection thus avoiding the need for invasive tumour biopsies. The study identified two agents with clinically relevant activity observed in the ctDNA mutation positive cohorts (Lancet Oncol 2020). In upper tract urothelial cancer we have demonstrated that adjuvant chemotherapy improves outcomes for patients (The Lancet 2020) and 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 (Lancet Oncol. 2020).

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).

We are a multi-disciplinary CTU, with more than 90 staff including statisticians/trial methodologists, clinical trial programme managers, trial managers, data managers, research IT programmers and administrative support staff.

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.

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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

Duties and responsibilities

Main purpose of the job

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.

Key duties

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:

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

Data Manager

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

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.

Data Manager

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

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

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About our organisation

The Institute of Cancer Research, London, is one of the world's most influential cancer research institutions, with an outstanding track record of achievement dating back more than 100 years. Our mission is to make the discoveries that defeat cancer.

As well as being one of the UK's leading higher education institutions in research quality and impact, the ICR is consistently ranked as one of the world's most successful for industry collaboration. As a member institution of the University of London, we also provide postgraduate higher education of international distinction.

We are also a charity and rely on the support of partner organisations, funders, donors and the general public.

Read more to find out more about our history, culture, and achievements, and how our funders, supporters and partnerships help drive forward our work.

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'.

> ***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."*
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> **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

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.