ICR The Institute of Cancer Research

in partnership with CANCER RESEARCH UK

JOB DESCRIPTION

JOB TITLE:	Data Linkage Specialist
POST NUMBER:	925
DIVISION & TEAM:	Division of Clinical Studies Clinical Trials and Statistics Unit (ICR-CTSU)
GRADE:	Clinical Trials Research Fellow / Assistant
RESPONSIBLE TO:	Principal Statistician, ICR-CTSU
ACCOUNTABLE TO:	Professor Judith Bliss Director ICR-CTSU

BACKGROUND

The Institute of Cancer Research, London, is one of the world's most influential cancer research organisations, with an outstanding record of achievement dating back more than 100 years. We provided the first convincing evidence that DNA damage is the basic cause of cancer, laying the foundation for the now universally accepted idea that cancer is a genetic disease. Today, we are world leaders in discovering new targeted cancer drugs, identifying new cancer genes and developing new forms of precision radiotherapy.

Under the leadership of our Chief Executive and President, Professor Paul Workman FRS, The Institute of Cancer Research (ICR) is ranked as the UK's leading higher education institution for the quality and impact of its research. Together with our partner The Royal Marsden NHS Foundation Trust (RM), we are rated in the top four centres for cancer research and treatment worldwide.

The ICR is committed to attracting and developing the best minds in the world to join us in our mission – to make the discoveries that defeat cancer.

The ICR-CTSU is an internationally recognised cancer clinical trials unit (CTU) with over 25 years' experience in the design, conduct and analysis of cancer clinical trials. ICR-CTSU receives programmatic core funding from Cancer Research UK (CRUK), is a UK Clinical Research Collaborative (UKCRC) registered CTU and is one of fifteen CTUs recognised by the UK National Cancer Research Institute (NCRI) 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 which will ultimately translate into patient benefit internationally. ICR-CTSU's main interests and areas of expertise are phase II/III randomised trials that evaluate new drug treatments and technologies (including radiotherapy) and/or utilise biomarker-driven designs to clinically qualify putative predictive biomarkers and evaluate targeted treatments.

Our portfolio includes innovative, efficient and adaptive trial platforms. We have a large network of collaborations within the clinical and academic community and with the pharmaceutical industry.

Our portfolio of national and international trials prioritises activity in three clinical and therapeutic domains:

- Breast cancer systemic therapies and uncommon cancers
- Urological and lung cancer systemic therapies and early phase trials
- Image-guided and local therapies

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.

Recent 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 IMPORT-Low trial, nominated for BMJ trial of the year 2018, provides evidence to support the use of less (partial rather than whole breast), but equally effective, radiotherapy for selected breast cancer patients (Lancet 2017 390(10099):1048-1060) and is the most recent of our long-standing portfolio of phase III radiotherapy trials to report practice changing results. We have recently been awarded funding for the UK's first trial of proton beam therapy (Clin Oncol 2018. 30(5):274-6).

The ICR-CTSU is a multi-disciplinary CTU, which comprises more than 90 staff including statisticians, clinical trial programme managers, trial managers, data managers, research IT programmers and administrative support staff. In February 2019 we had 100 active grants and were in receipt of grant income (including from pharma partners) >£7M. We have 75 multi-centre trials on our portfolio in set-up (7), open to recruitment (17), in active or long-term follow-up (43) totalling over 25,000 patients and 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:
www.icr.ac.uk | **Twitter** @ICRnews | **Facebook**
www.facebook.com/theinstituteofcancerresearch

BACKGROUND TO THE ROLE

Randomised controlled trials (RCTs) are recognised to be the most scientifically rigorous method for hypothesis testing and considered the gold standard approach to evaluate the effectiveness of a treatment intervention. However, the assessment of both disease-related outcomes and treatment-related sequelae can be challenging for trialists and can come at a considerable cost to both research funders and participating NHS provider sites particularly when the measurement of long-term or late effects over many years is important. Coupled with competing pressures within the clinical setting, which increasingly threaten the requisite follow-up information being completed, there is an increasing resolve within the clinical trials community to minimise data collected via completion of case report forms (CRFs) and advocate the use of routinely collected data sources (e.g. using data collected via registries, hospital episode statistics) and patient reported outcomes. Before trials can use routine data the reliability of these datasets to be able to replace trial-specific CRF data collection via centres in order to provide robust assessments of common cancer trial endpoints and the validity of using routine data for clinical outcomes in trials must be confirmed.

The post holder will have a varied role working on a number of projects to integrate routinely collected and patient reported outcomes into clinical trial datasets for analysis. A key project will focus on validating routine datasets within four existing breast cancer trials and supporting prospective use of routine data within clinical trials (e.g. using hospital episodes statistics for health economic evaluation). In addition the post holder will have opportunities to work on statistical development and analysis exploring alternative methods of data collection (e.g. using electronic data capture for quality of life outcomes) and working with teams such as the ICR Knowledge Hub to explore how use of technology and 'Big Data' can increase the output from trials.

It is anticipated that the post holder will become the Unit's lead for applications to bodies such as Public Health England and NHS Digital to access individual patient level data to support clinical trial data collection and analysis providing data linkage expertise to colleagues with ICR-CTSU and external collaborators associated with our trials.

DUTIES AND RESPONSIBILITIES

The post holder will work under the guidance of the ICR-CTSU Director and Deputy Directors with additional mentorship/support provided by an ICR-CTSU Principal Statistician and Clinical Trials Data Management Specialist as required. Specific duties and responsibilities will include some or all of the following:

Utilising routine datasets in clinical trials

- Assess reliability and validity of datasets processed by the National Cancer Registration and Analysis Service (NCRAS) as an alternative data source using existing breast cancer clinical datasets. Specific aims include:
    - Identify and quantify number of trial participants within each relevant routine dataset.
    - Conduct an objective assessment of NCRAS data completeness, validity, and consistency with trial data.
    - Cross-comparison of trial baseline and treatment data.

  - Cross-comparison of emerging disease related outcome data including development and validation of algorithms to determine recurrence episodes.
  - Collection of incidence of co-morbidities (identification of long-term safety data).
  - Representativeness of trial patient vs. general population matched to the trial's main criteria.
- Scope opportunities to utilise routinely collected data on trial participants across the range of disease sites and interventions studied as part of ICR-CTSU's trial portfolio.
- Support development and implementation of ICR-CTSU strategy for efficient integration of routine data into clinical trials.
- Collaborate on relevant methodological projects with researchers (e.g. across the UKCRC Registered CTU network) as required.
- Maintain a thorough understanding of current regulation and governance concerning data processing and linkage and contribute to the development and maintenance of ICR-CTSU quality processes in this area.
- With the Clinical Trials IT Manager and Clinical Trials Data Management Specialist develop systems and processes to facilitate secure linkage of external data sources with existing trial data held by ICR-CTSU ensuring compliance with regulatory requirements.

Trial development and design

- Develop and define the study question as part of the Protocol Development Group (with clinical colleagues, proposed chief investigator, clinical trial unit leads). This will often include a review of the available literature and analysis of data available from other sources including interrogation of routine datasets to address feasibility questions.
- Contribute to clinical trial grant applications in collaboration with the Protocol Development Group through advice on use of routine datasets.
- Contribute as required to submissions to Competent Authority, Research Ethics Committees, Public Health England and NHS Digital.
- Develop the trial protocol with Protocol Development Group, particularly the statistical considerations of sample size and analysis strategy and strategies for data collection.
- Contribute to the design of (electronic-) Case Report Forms and trial databases to ensure data are collected, stored and integrated to meet the requirements of statistical monitoring and analysis, and in line with relevant guidelines and legislation (e.g. Data Protection Act, EU Clinical Trials Directive, Research Governance Framework, ICH Statistical Principles for Clinical Trials, Good Clinical Practice).
- Work with IT programming/database staff to set-up, test and maintain trial databases (including randomisation systems).

Trial management and analysis

Dependent on successful funding applications and location of research, the data linkage statistician may provide day-to-day statistical support for trials using routine data/alternative data collection methods. Responsibilities could include:

- 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.
- Liaise with trial managers/data managers to ensure completeness and correctness of data during both recruitment and follow-up phases of trials.
- Enter and/or check trial data if required to meet trial deadlines.
- With the trial manager, ensure accurate and consistent coding of clinical data.
- Undertake central statistical monitoring of data to assist audit and quality control.
- Assist the trial manager in the preparation of data for regular safety reporting to the competent authority, ethics committees and Sponsor.
- Assist the trial manager in the preparation of reports for Trial Management Group and Trial Steering Committee meetings.
- Undertake interim analyses and produce reports for submission to the Independent Data Monitoring Committee.
- Undertake final analyses and compilation of reports for presentation and publication.
- Undertake additional analyses, exploring novel methodologies as required.
- Liaise and work with bioinformaticians, translational analysts and clinical investigators, 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).
- 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 UKCRC Registered Clinical Trials Units) to develop professional specialism.
- Keep up to date with the related medical and statistical literature.

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 CIs.
- Promote the work of ICR-CTSU by presenting methodology output at national/international symposia.
- With statistical colleagues, monthly review of Royal Marsden Hospital (RM)/ICR research projects submitted to the RM/ICR Committee for Clinical Research. This includes review of sample size calculations and statistical methodology.
- Be familiar with trials randomised via ICR-CTSU in order to provide a competent telephone randomisation service and be able to enter patients as appropriate by telephone, fax or email. In some cases this will involve resolving queries with the clinician regarding the suitability of the patient for entry into the trial. ICR-CTSU's randomisation telephone line is manned 9am-5pm each working day on a rota basis.
- Contribute to monthly meetings of ICR-CTSU and RM based statisticians and to the ICR-CTSU monthly journal review.

- 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 medical 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.

Any other duties which may be required which are consistent with the nature and grade of the post.

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.

HOURS OF WORK:
Contracted hours of work are usually 09.00 to 17.00 Monday to Friday, although the post holder would be expected to work flexible hours if necessary to meet deadlines. It may be necessary for the post holder to be available for occasional evening meetings and for meetings involving overnight stays, possibly including visits abroad. Occasional travel will be required.

APPOINTMENT DETAILS:
Appointment will be on a Fixed Term Contract for 2 years in the first instance, with the possibility of renewal.

Appointment will be made to the Epidemiology/Clinical Trials Research Assistant (EPRA) or Research Fellow (EPRF) scale, with exact salary dependent on skills, qualifications and experience. The EPRA scale commences at £32,200 rising to £35,500 per annum and EPRF scale commences at £37,850 rising to £43,500 per annum. This is a new post funded from Cancer Research UK. Progression through the salary scale is performance related.

The post holder will receive a generous annual leave entitlement. There is also an entitlement to 11 days public and privilege holidays.

The post is based at the ICR site at Sutton, Surrey.

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 development.

October 2019

PERSON SPECIFICATION

Criteria	Essential or Desirable?
Education & Knowledge	
Post-graduate qualification in statistics or an allied field (e.g. public health, epidemiology, data science) or degree with substantive statistical component and practical experience in medical statistics.	Essential
Higher degree (MSc or PhD) in medical statistics or an allied field (e.g. public health, epidemiology, data science).	Desirable
A sound understanding of the concept of randomised 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
Experience	
Applying statistical methods to real data.	Essential
Management, manipulation and merging of large and complex datasets	Essential
Familiarity with clinical trials procedures.	Desirable*
Working in clinical trials, epidemiology or an allied research field in a statistical capacity.	Desirable*
Statistical and critical review of documents.	Desirable
Sample size calculations.	Desirable
Designing clinical studies.	Desirable
Statistical consulting.	Desirable
Performing literature reviews.	Desirable
Survival analysis methods.	Desirable
Analysing longitudinal data sets.	Desirable
Working as an applied medical statistician within academia or the pharmaceutical industry.	Desirable
Working in the medical/cancer field.	Desirable

Skills	
Working knowledge of statistical software (e.g. STATA, R, SAS, nQuery).	Essential
Excellent knowledge of PC based Windows and Microsoft Office software.	Essential
Excellent knowledge of databases (e.g. Access) and strong data management and manipulation skills.	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 randomised 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 trial collaborators.	Essential
Ability to draft relatively routine correspondence and newsletters.	Essential
Interest in developing trials conduct research around the use of routine datasets or electronically collected patient reported outcomes.	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
Right to work in the UK	Essential
Experience of handling sensitive and confidential information.	Desirable
Motivated to publish independent research	Desirable

* Essential for appointment at EPRF level