JOB DESCRIPTION

Job Title: Translational Statistician/Biostatistician
Division: Clinical Studies
Team: Clinical Trials and Statistics Unit (ICR-CTSU)
Grade: Clinical Trials Research Fellow/Assistant
Responsible to: Dr Maggie Cheang
Team Leader, Genomic Analysis – ICR-CTSU
Accountable to: Professor Judith Bliss,
Director ICR-CTSU, Deputy Head, Division of Clinical Studies

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 Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU) manages an exciting portfolio of national and international phase III multi-centre randomised controlled trials, and phase II trials of targeted treatments. The portfolio has a special emphasis on trials of breast and urological cancer treatments, and an expanding number of trials in rare cancers. Many of our trials have linked sample collections on which associated biomarker translational research is based. Increasingly, as we pursue a personalised medicine approach to cancer treatment, biomarkers are being used to select potential trial participants and monitor their progress.

We are seeking a biostatistician with a special interest in developing a career in correlative science and biomarker research to join our translational research efforts within the ICR-CTSU. The successful individual will be in a key interface position, supporting initiatives to integrative analysis of biomarker data from next generation sequence (NGS), gene expression profile, proteomics and immunohistochemical platforms with patients’ outcome data from clinical trials.
DUTIES AND RESPONSIBILITIES:

Working under the guidance of the ICR-CTSU Genomic Analysis Team Lead, Principal Statistician and ICR-CTSU Scientific Lead, the post holder will have responsibilities in the areas detailed below. Please note training will be provided as required depending on the current skills and experience of the successful applicant:

Management and analysis of clinical and translational data:

- Interrogate clinical outcomes data to clinically qualify biomarkers of interest.
- Develop and define biological statistical analysis plans.
- Apply as appropriate data interrogation methods and advanced multivariate statistical methods.
- Perform analyses on biological data generated from exome and whole genome sequencing, proteomics, RNA-seq and/or digital gene expression profiles data with patients outcome in clinical trials.
- Integration and visualisation of biomarker datasets from clinical and multiple high-throughput genomics platforms.
- Work with IT programming/database staff to set-up, test and maintain translational databases as required.

Trial Initiation and design

- Develop the (biological) statistical analysis plan ensuring compliance with relevant guidelines.
- Contribute to the development of (biomarker-related) trial literature (e.g. patient information leaflets and ethics committee submissions).
- Liaise and collaborate with trial co-coordinators and specialist advisors working on translational studies / clinical trials.
- Contribute to submission to grant awarding bodies for external funding of specific translational/clinical trial projects as appropriate.
- Develop and define appropriate translational or biomarker study/clinical trial questions and endpoints with Protocol Development Group (with clinical colleagues, translational expert, proposed chief investigator, ICR-CTSU Scientific lead, trial statistician) including, as appropriate, a review of the available literature and analysis of data available from other sources.
- Develop the translational sub-study protocol/study protocol with Protocol Development Group, particularly the statistical considerations of endpoint definition, sample size and data collection tools/methods.

Management and analysis of trials

- Perform exploratory data analyses.
- Contribute to the drafting of translational/biomarker focused manuscripts for scientific publication.
- Research and utilise appropriate statistical methodologies. Work with statistical colleagues to develop or modify novel statistical methodology as required by each analysis. This may include collaboration with others with similar interests to develop professional specialism.
- Explore opportunities for appropriate analysis of data from similar studies in order to perform a systematic overview or meta-analysis.
- Assist and advise the trial team on their work to ensure completeness and correctness of trial data, in all aspects related to biological data and liaisons with the different collaborating laboratories.
- Assist the trial manager in the preparation of reports for Trial Management Group and Trial Steering Committee meetings in the specific translational aspects of the main trial.
- Assist the trial statistician in the reports for the Independent Data Monitoring Committee meetings in the specific translational aspects of the main trial.
Undertake or assist the trial statistician in the final analyses of the translational/biomarker endpoints. Compilation of reports for presentation and publication.

Other duties

- Keep up to date with the related medical, bioinformatics and statistical literature.
- Actively contribute to national citizenship in areas of statistical aspects of translational research (e.g. membership of Data Monitoring, ethics or R&D committees, editorial boards, journal reviews).
- With statistical colleagues, monthly review of Royal Marsden Hospital (RM) or ICR research projects submitted to the joint RM/ICR Committee for Clinical Research.
- Contribute to monthly meetings of ICR-CTSU statisticians and ICR bioinformaticians and to the ICR-CTSU monthly journal review.
- Provide occasional consulting advice to clinical and scientific colleagues and occasional lectures on 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.
**APPOINTMENT DETAILS**
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.

Appointment will be on a Fixed Term Contract for 3 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 £44,337.

The annual leave entitlement is 28 days per annum. There is also an entitlement to 11 days public and privilege holidays.

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

**FURTHER INFORMATION**
You may contact a member of the ICR-CTSU for further information by emailing ctsu@icr.ac.uk

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.
## PERSON SPECIFICATION

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<th>EDUCATION/KNOWLEDGE</th>
<th>Essential/Desirable</th>
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<tr>
<td>Higher degree (MSc or PhD) in medical/biostatistics or an area allied to translational research or first degree in (bio)statistics, bioinformatics, mathematics or a related field with a strong statistical / mathematical component with equivalent working experience. Post-graduate qualification in biostatistics, bioinformatics, computer science or related field.</td>
<td>Essential/Desirable</td>
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<td>Proficient knowledge of cancer genetics.</td>
<td>Desirable</td>
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<td>Understanding of the concepts of SNPs, next-generation sequencing, statistical genetics</td>
<td>Desirable</td>
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<td>A good understanding of cancer and its treatment modalities.</td>
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<td>A sound understanding of the concept of randomised clinical trials. Knowledge of Good Clinical Practice, the EU Clinical Trials Directive, Research Governance Framework, ICH Statistical Principles for Clinical Trials.</td>
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<td>Experience of analysing biomarker or genetic/genomic data and associated clinical data.</td>
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<td>Experience of working as an applied translational statistician/analyst within academia or the pharmaceutical industry.</td>
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<td>Experience of working as a clinical trials statistician.</td>
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<td>Experience of applying data interrogation and/or multivariate statistical methods.</td>
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<td>Experience in data integration and visualisation</td>
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<td>Experience with regression modelling in survival analysis, development and validation of prognostic and predictive models.</td>
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<td>Experience in relational databases</td>
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<td>Experience of and familiarity with clinical trials procedures.</td>
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<td>Experience with sample size calculations.</td>
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<td>Experience of working in the cancer field.</td>
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<td>Statistical experience of clinical trials, epidemiology or an allied research field.</td>
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<td>Experience of statistical and critical review of documents.</td>
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<th>SKILLS</th>
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<td>Working knowledge of statistical software (e.g. R, STATA, SAS).</td>
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<td>Scripting experience in Unix/Linux</td>
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<td>Excellent written and spoken English</td>
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<td>Effective oral and written communication skills.</td>
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<td>Excellent organisational and time management skills; ability to organise and prioritise both personal and project workload.</td>
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<td>Ability to work accurately, with a strong attention to detail.</td>
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Excellent interpersonal skills to facilitate liaison with colleagues and trial collaborators. | Essential

**GENERAL**

Ability to project a positive and professional image of the ICR-CTSU both to 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 working on and with a trial management committee. | Desirable

Experience of handling sensitive and confidential information. | Desirable
BACKGROUND INFORMATION

The Institute of Cancer Research (ICR)
The ICR, which is an independent college of the University of London, is a world-class cancer research organisation with HEFCE RAE ratings of international excellence across all of its research programmes. In partnership with The Royal Marsden NHS Foundation Trust (RM) we form the largest comprehensive cancer centre in Europe, employing several thousand staff. We are dedicated to basic, clinical and translational research that extends from epidemiology, genetics and molecular biology, through drug discovery and development and clinical trials, to cancer diagnosis and patient treatment with our overall mission being the relief of suffering from cancer. The joint organisation is at the forefront of international cancer research, and has many of the necessary components in place to continue to make a considerable impact in developing personalised medicine.

Further information is available at: www.icr.ac.uk | Twitter @ICR_London | Facebook www.facebook.com/theinstituteofcancerresearch

The ICR Clinical Trials and Statistics Unit (ICR-CTSU)
The ICR-CTSU, led by Professor Judith Bliss, is a Cancer Research UK core funded clinical trial unit (CTU); it is UK Clinical Research Collaborative (UKCRC) registered 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. Within the context of ICR/RM’s strategy of developing precision medicine, ICR-CTSU aims to initiate, conduct and analyse clinical trials that will be at the forefront of changes to clinical practice within the National Health Service and overseas. 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. ICR-CTSU’s clinical areas of focus are breast, urological and head and neck cancers with further trials in melanoma, sarcoma, renal cell and ovarian cancer.

Recent investment at ICR/RM with the NIHR Centre for Molecular Pathology, Tumour Profiling Unit and Cancer Research UK Imaging Centre, including investment in bioinformatics with research teams dedicated to computational biology, and computational genomics, makes ICR-CTSU ideally placed to further develop its portfolio of biomarker driven trials, to clinically qualify putative biomarkers and to drive innovation in how clinical trials results are utilised. Working in partnership with the National Cancer Research Institute Clinical Studies Groups, internationally respected clinical and scientific research leads, ICR-CTSU trials aim to enhance scientific discovery and inform clinical practice.

The ICR-CTSU is a multi-disciplinary CTU, which comprises more than 80 staff including statisticians, trials managers, data mangers and research, IT and administrative support staff. Staff are managed within a scientific and professional specialty matrix with statistical and trial management staff under the scientific leadership of the Director or Deputy Director, and trial management, IT and administration staff under the operational leadership of the Operations Director. ICR-CTSU scientific and statistical leadership for individual trials is provided by the Director or Deputy Director.

For further information see: http://www.icr.ac.uk/research/research_divisions/Clinical_Studies/clinical_trials/index.shtml
Twitter @ICR_CTSU

Location
The ICR site at Sutton has on-site sports and social facilities including a gym, sports hall and a bar. Sutton is situated within an easy commute of central London and has excellent train and bus links ensuring easy access for professional and personal opportunities. Gatwick Airport is approximately 30 minutes away by car. Sutton is close to the North Downs and Surrey Hills, areas with pleasant walks, cycling and a wide range of outdoor activities.