INSTITUTE OF CANCER RESEARCH

JOB DESCRIPTION

JOB TITLE: Clinical Trials Programme Manager (CTPM)

DIVISION: Clinical Studies

TEAM: Clinical Trials & Statistics Unit (ICR-CTSU)

GRADE: Senior Scientific Officer

RESPONSIBLE TO: Director or Deputy Director, ICR-CTSU

ACCOUNTABLE TO: Judith Bliss, ICR-CTSU Director
Claire Snowdon, ICR-CTSU Deputy Director & Operations Director

BACKGROUND

All ICR-CTSU trials fall under the scientific and methodological leadership of either the Director or the Deputy Director. Clinical Trials Programme Managers (CTPMs) working under the direction of the scientific lead and Operations Director are each responsible for overseeing a component of the trials portfolio, ensuring trials are initiated and delivered effectively. In addition to dedicated statistical and IT support, each trial has a trial team comprising of trial management, data management and administrative support. The CTPM is responsible for the development and initiation of new trials and for overseeing the trial team, ensuring staff are suitably trained and supported. In addition, CTPMs are expected to provide scientific or operational expertise and leadership within a defined area of research or trial conduct.

RESPONSIBILITIES/DUTIES

1. Development and set up of new studies/sub studies in the context of relevant local, national and international priorities and ongoing research interests. This includes:

    - Developing successful funding applications; contributing to the scientific, financial and trial management aspects of the application;
    - Ensuring effective and timely site feasibility assessments;
    - Developing study protocols and patient information material, ensuring compliance with the highest scientific, regulatory and ethical standards;
    - Ensuring appropriate sponsorship arrangements are in place for the conduct of the study;
    - Liaising with the ICR contracts managers, sponsor organisations, key collaborators and pharmaceutical partners to ensure appropriate contractual arrangements for trial conduct are in place;
    - Negotiating with external collaborators, including pharmaceutical partners, to ensure effective provision of protocol treatments;

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- Obtaining regulatory, ethics and HRA approvals for trial conduct;
- Ensuring successful launch of new trials, including presentations at investigator meetings, in conjunction with the Chief Investigator (CI) and the trial manager.

2. Overseeing the conduct of a number of studies within the ICR-CTSU portfolio to ensure their smooth running and progress, including:

    - Working closely with ICR-CTSU scientific leads, CIs, trial oversight committees, sponsor organisations and study teams to ensure effective communication between all parties;
    - Overseeing trial team, ensuring appropriate arrangements are in place for the delivery and management of study treatment and the collection of high quality data and biological specimens;
    - Continually reviewing milestones and timelines to ensure effective conduct and timely reporting across the studies, including annual progress and safety reporting to regulators and ethics committees;
    - Producing and/or reviewing reports to funders and other key organisations, e.g. Cancer Research UK, National Institute for Health Research (NIHR), National Cancer Research Institute (NCRI);
    - Producing and/or reviewing reports to trial oversight committees, including the Trial Management Group (TMG), Trial Steering Committee (TSC) and, if required, the Independent Data Monitoring Committee (IDMC) and attending meetings of those committees as necessary.

3. Contributing to ICR-CTSU's scientific output, including:

    - Providing oversight of key aspects of research within the post-holder's trials portfolio;
    - Identifying and conducting additional research which supports ongoing and/or proposed trials;
    - Drafting clinical trial and methodology abstracts and publications in conjunction with CIs, trial managers and statisticians, as required.

4. Line management of a team of trial staff within the agreed portfolio, including:

    - Leading, motivating and developing staff within the team;
    - Prioritising and allocating workloads within the team to ensure effective delivery of the portfolio;
    - Identifying the training requirements of the team to ensure operational objectives and, where appropriate, personal development goals are met;
    - Providing and / or co-ordinating training and support where required;
    - Conducting annual appraisals to review progress, set objectives and identify areas for development;
    - Dealing with any staffing issues that may arise through the application of ICR performance management procedures.

5. Contributing to the ICR-CTSU Quality Management System (QMS), including:

    - Assisting with the preparation and conduct for any GCP inspection or 3rd party audit within ICR-CTSU;

- Contributing to the review of ICR-CTSU systems and processes to ensure continued compliance with relevant legislation;
- Contributing to Quality Assurance Review Team meetings or other working groups to facilitate implementation of the QMS across the trial portfolio;
- Advising and supporting staff on the ethical principles, research governance and regulatory standards for the conduct of clinical trials;
- Assisting with the audit of trials activity within the Unit.

6. Proactive member of ICR-CTSU's Management Group, including:

- Attending and contributing to regular management and operational meetings with other senior staff;
- Contributing to regular team meetings and providing feedback at those meetings on behalf of the Management Group;
- Leading and promoting new initiatives within ICR-CTSU;
- Assisting with the preparation for the CR UK quinquennial reviews, working with other senior staff and delegating tasks as necessary;
- Undertaking occasional teaching sessions and formal presentations both within ICR and externally;
- Developing links with external national bodies and trial related groups

7. Undertaking any other duties as may be required, consistent with the nature and grade of the post.

8. 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.

APPOINTMENT DETAILS

This position is offered full time (35 hours per week) or part time (+21 hours per week). In general ICR-CTSU staff work from 9 am to 5 pm with a one hour lunch break. Flexibility around core hours (10 am to 4 pm) is permitted. The post holder may be required to work outside these hours to meet deadlines. It may also be necessary for the post holder to be available for occasional evening meetings and for meetings to include overnight stops.

Appointment will be on a Fixed Term Contract for 3 years initially.

Appointment will be to the Senior Scientific Officer (SSO) scale, with exact salary dependent on skills, qualifications and experience. The SSO scale commences at £42,792 p.a. rising to £50,943 p.a. Progression through the salary scale will be performance related. In addition the salary scales are reviewed annually to reflect cost of living increases.

The annual leave entitlement is 25 days pa rising to 30 days for every 2 years worked. In addition there is 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 developments.

January 2019

The Institute of Cancer Research

PERSON SPECIFICATION

JOB TITLE: Clinical Trials Programme Manager

DIVISION: Clinical Studies

	Essential	Desirable
EDUCATION/KNOWLEDGE		
Minimum of a first degree or equivalent qualification in biomedical sciences or an allied subject (including health care disciplines)	✓	
Postgraduate qualification in biomedical sciences or an allied subject		✓
SKILLS & EXPERIENCE		
Proven track record working at a senior level (i.e. management team or equivalent) within a research oriented group	✓	
Experience of managing, directing and supporting staff	✓	
Proven project management / central coordination experience gained in the phase II or III multi-centre trial setting	✓	
Experience/knowledge of the current UK ethics and regulatory processes associated with clinical research	✓	
Excellent knowledge of the EU Clinical Trials Directive, UK Clinical Trials Regulations, Principles of Good Clinical Practice and research governance framework legislation together with the ability to disseminate the knowledge and information	✓	
Experience of scientific and logistical input into trial documentation including protocol, CRFs, manuscripts and reports.	✓	
Experience of biomarker driven research		✓
Experience/knowledge of laboratory quality systems and procedures		✓
Experience of working in an academic research environment		✓
Experience of working in oncology or related fields (i.e. radiotherapy)		✓
Experience of developing/managing quality assurance documentation and systems		✓
Experience of successful grant submissions		✓
Experience of preparing for regulatory/sponsor inspection		✓
Experience of negotiations with external organisations such as funding bodies, Chief Investigators, sponsors, pharmaceutical companies		✓

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	Essential	Desirable
Up to date knowledge of current data and views of experts in relevant fields e.g. NCRI Clinical Studies Groups, Cochrane Collaboration.		✓
Experience of scientific report writing (e.g. clinical study report, peer reviewed publication)		✓
Experience of preparing and delivering complex presentations and reports at national /international meetings		✓
GENERAL		
Ability to work with others within a multidisciplinary team and to work independently	✓	
Ability to project a positive and professional image of ICR-CTSU to stakeholders from the UK and overseas	✓	
Interest in developing research proposals that are compatible with ICR-CTSU's overall scientific strategy	✓	
Excellent organisational and time management skills to manage and deliver a range of tasks and projects to tight deadlines	✓	
Proven interpersonal and communication skills to: • work as a team player and foster a team environment; and • communicate effectively with internal colleagues and external collaborators; • manage staff	✓	
Good IT skills	✓	
Excellent presentation skills	✓	
Ability to make effective and enthusiastic contributions to scientific and management meetings	✓	
Ability to work with clinical and management colleagues at all levels across a range of organisations	✓	
Right to work in the UK	✓	
Ability to chair meetings effectively		✓
Availability and willingness to travel (on occasion)		✓
PERSONAL QUALITIES		
Flexible and innovative approach to working, including problem solving through lateral thought, management of change and a desire to develop knowledge	✓	
Highly motivated with the ability to influence and inspire others	✓	
Effective decision maker	✓	
Ability to work effectively under direction and on own initiative	✓	
Strong attention to detail	✓	

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** @ICRnews | **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 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.

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.

We manage an exciting portfolio of national and international phase III multi-centre randomised controlled trials, and phase II trials of targeted treatments. Our portfolio prioritises activity in three clinical domains:

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

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 clinical trials unit, which comprises more than 90 staff including statisticians, trials managers/co-ordinators, data managers 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 (Professor Bliss) or Deputy Director (Professor Hall), and trial management, IT and administration staff under the operational leadership of the Operations Director. ICR-CTSU scientific and methodological 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

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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.