ICR The Institute of Cancer Research

Quality Assurance and Pharmacovigilance Officer

Candidate Information

January 2023

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. We are world leaders in identifying cancer genes, discovering cancer 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 came top in the league table of university research quality compiled from the Research Excellence Framework (REF 2014).

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 (CTSU)

The ICR-CTSU is an internationally recognised, methodologist-led academic cancer 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, is a UK Clinical Research Collaboration registered CTU and is one of fifteen CTUs recognised by the UK National Cancer Research Institute 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 high quality and efficient cutting-edge trials of smarter, kinder treatments which will ultimately translate into patient benefit internationally. Our main interests and areas of expertise are the evaluation of new drug and radiation treatments and the use of biomarker-driven designs to clinically qualify putative predictive biomarkers and evaluate targeted treatments. Our portfolio spans both early and later phase studies, and 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 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, upper tract urothelial, ovarian, testicular, penile) Our cross-cutting biomarker and genomic analysis theme 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. We also provide methodology leadership to an expanding number of early phase I cancer trials run in collaboration with the Drug Development Unit, a joint unit of ICR and The Royal Marsden NHS Foundation Trust and a leading phase I unit globally.

Some highlights which demonstrate the breadth and impact of our portfolio include: The FAST-FORWARD trial provides evidence that a one-week course of radiotherapy in fewer but larger daily doses is as safe as the standard three-week therapy for women following surgery for early stage breast cancer (Lancet 2020 395(10237): 1613-1626) 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 downstream treatment cohorts identified two agents with clinically relevant activity observed in the ctDNA mutation positive cohorts (Lancet Oncol 2020; 21: 1296–308). In upper tract urothelial cancer we have demonstrated that adjuvant chemotherapy improves outcomes for patients (The Lancet 2020; 395: 1268-77) 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; 21:162-74).

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, a quality assurance review team and administrative support staff.

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. Our senior management team hold leadership roles shaping clinical research at the local, national and international level.

The Drug Development Unit (DDU)

The Drug Development Unit (DDU) is a joint unit of The Royal Marsden and the ICR which specialises in first-in-human trials and provides a pathway from pre clinical drug discovery through to proof of principle phase I trials and tumour specific evaluation of novel agents. The unit treats close to 300 patients a year on Phase I trials, making it one of the largest facilities of its kind in the world. The Unit takes at least three to four novel drugs forward to

the next stages of development every year, including those discovered at the ICR. The unit is supported by Cancer Research UK, an Experimental Cancer Medicine Centre (ECMC) grant, and a core grant from the Biomedical Research Centre at The Royal Marsden and the ICR. It's unique infrastructure and capabilities allow DDU to sponsor, design, execute and report biomarker-driven, early phase trials though the investigator-initiated trials (IIT) team. The team works in collaboration with commercial and academic partners to take forward promising novel therapies or therapy combinations which would otherwise not progress, to address unmet clinical needs.

Further information is available at:

ICR	www.icr.ac.uk | **Twitter** @ICR_London| **Facebook** www.facebook.com/theinstituteofcancerresearch
ICR-CTSU	**Twitter** @ICR_CTSU | https://www.icr.ac.uk/our-research/centres-and-collaborations/centres-at-the-icr/clinical-trials-and-statistics-unit
ICR-DDU	**Twitter** @ICR_DDU_IIT

Our mission is to make the discoveries that defeat cancer.

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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

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Job description

Department / division:	Division of Clinical Studies, ICR-CTSU & DDU
Pay grade / staff group:	Research Management 2
Hours / duration:	Full time (35 hours per week), Monday to Friday. Fixed term contract for 2 years
Reports to:	ICR-CTSU Assistant Operations Director
Accountable to:	ICR-CTSU Operations Director and DDU Head of Investigator Initiated Research
Main purpose of the job:	Quality and pharmacovigilance oversight of ICR-CTSU and DDU trials activity

Role Summary:

We would like to appoint a Quality Assurance and Pharmacovigilance Officer to provide a dedicated resource to members of the ICR-CTSU/DDU Quality Assurance Review Team to provide continued quality oversight of our trials activity and to ensure on-going compliance with applicable regulatory standards. The post holder will be responsible to the ICR-CTSU Assistant Operations Director and DDU Head of Investigator Initiated Research and will work as part of the joint ICR-CTSU/DDU Quality Assurance Review Team (a multidisciplinary team of trial managers, statisticians, data managers, IT specialists and research administrators with responsibility for on-going review of the quality management system and quality assurance activities).

The post holder will coordinate and conduct audits of clinical trial documentation and procedures and be responsible for ensuring procedures are fit for purpose and commensurate with level of risk. The post holder will also be responsible for quality control of pharmacovigilance activities and be a pro-active member of the ICR-CTSU/DDU pharmacovigilance working group. The post holder will provide quality assurance and pharmacovigilance advice and support to colleagues within ICR-CTSU and DDU and represent ICR-CTSU and DDU at relevant meetings within the wider ICR and Royal Marsden (RM) institutions and nationally, as required.

In general ICR-CTSU/DDU staff work from 9 am to 5 pm with a one hour lunch break. However, the post holder may occasionally be required to work outside these hours to meet deadlines. Flexible working options, including hybrid working, may be considered.

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Duties and responsibilities:

Quality Assurance

Create SOPs to cover those duties carried out by the Quality Assurance Officer and assist in the preparation of other SOPs where relevant.
Be an active member of the joint ICR-CTSU/DDU Quality Assurance Review Team, contributing to the review of existing quality systems and procedures, identifying areas for improvement as necessary.
Support the administration of the electronic platform for ICR-CTSU and DDU's quality management system (Q-Pulse).
Provide quality assurance advice and training to ICR-CTSU and DDU staff.
Develop expertise in clinical trials quality assurance in order to represent ICR-CTSU and DDU at relevant local and national meetings as required.
Liaise with colleagues in the wider ICR and RM to ensure a consistent approach to quality management and attend relevant meetings as required, including those of the ICR/RM Risk Identification and SOP Working Group.

Audit

Under the guidance of the Assistant Operations Director, Head of Investigator Initiated Research and Deputy Director (Operations), plan and conduct a programme of regular systems, third party and trial master file audits and associated documentation to monitor adherence to SOPs and regulations.
Produce audit reports to document audit findings and follow up to ensure corrective actions are implemented.
Assist in the preparation for and coordination of regulatory and sponsor audits of ICR-CTSU and DDU and follow up any corrective actions to ensure they are implemented within specified timeframes.

Pharmacovigilance

Plan and conduct regular quality control checks of ICR-CTSU and DDU pharmacovigilance systems to ensure PV reporting is compliant with current regulations and relevant SOPs.
Provide Pharmacovigilance advice and training to ICR-CTSU staff.
Be an active member of the ICR-CTSU/DDU Pharmacovigilance Working Group, assist the group with planning bi-monthly meetings, setting agendas, preparing papers and writing minutes.

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Other

Participate in continuous professional development, keeping up-to-date with current legislation and practices and disseminate that knowledge effectively.
Advising ICR-CTSU and DDU teams on TMF archiving requirements, in line with the current regulations and relevant SOPs.
Other duties as required that are consistent with the nature of the role.

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Person specification

Education and Knowledge

Good first degree or equivalent in a relevant discipline	Essential
Working knowledge of Medicines for Human Use (Clinical Trials Regulations 2004 on Clinical Trials), Data Protection Act (1998), GCP and Research Governance	Essential
Certificate or equivalent in quality management	Desirable

Skills

Evidence of excellent organisational skills, including planning and prioritisation of tasks	Essential
Ability to communicate effectively verbally with staff at all levels, both within and outside the organisation	Essential
Ability to write clearly and concisely and thereby covey ideas effectively	Essential
Ability to critically review quality documentation, with a high attention to detail	Essential
Effective team working skills, including sensitive dealings with staff	Essential
Effective negotiation and facilitation skills	Essential
Evidence of IT literacy	Essential
Evidence of initiative, flexibility/pragmatism in previous employment	Essential
Ability to demonstrate enthusiasm and a high level of commitment to the requirements of the post and to the aims of the organisation	Essential

Experience

Experience in a quality assured clinical trials environment	Essential
Experience in pharmacovigilance processing, reporting or quality assurance	Desirable
Experience of performing audits	Essential
Experience of developing Standard Operating Procedures	Essential
Experience and evidence of working in a role requiring accuracy and attention to detail	Essential
Experience of management of a Quality Management System, preferably within a clinical trials environment	Essential
Previous experience and participation in a regulatory inspection	Desirable

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General

Ability to work independently and as part of a team	Essential
Ability to project a positive and professional image of the ICR-CTSU and DDU to both ICR and external collaborators	Essential
Ability to maintain adherence to written procedures and clinical and regulatory standards applicable to ICR-CTSU and DDU clinical trials	Essential
Experience of handling sensitive and confidential information	Desirable

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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 rising to 30 days and an additional entitlement of 11 days public and privilege holidays (pro rata for part time work).

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. 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.