ICR The Institute of Cancer Research

Quality Assurance Manager

Candidate Information

Jan 2025

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 are consistently in the top performing universities in the league table of university research quality compiled from the Research Excellence Framework (REF 2014 & 2021). 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 (ICR-CTSU)

Under the Directorship of Professor 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 a UK Clinical Research Collaborative Registered CTU.

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 how 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

ICR The Institute of Cancer Research

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, and we have an emerging portfolio of imaging biomarker studies.

We are a multi-disciplinary CTU, with more than 90 staff including statisticians/methodologists, clinical trial programme management, trial management, data management, research IT programming and administrative support staff. We are based at ICR's Sutton site.

The Drug Development Unit Investigator Initiated Trials (DDU IIT)

The Drug Development Unit (DDU), 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 our 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 in order to address unmet medical needs.

Further information is available at:

ICR www.icr.ac.uk | **Facebook** www.facebook.com/theinstituteofcancerresearch

ICR-CTSU www.icr.ac.uk/research-and-discoveries/centres-and-strategic-collaborations/clinical-trials-and-statistics-unit-icr-ctsu | **Bluesky** @icr-ctsu.bsky.social

Our mission is to make the discoveries that defeat cancer.

Quality Assurance Manager
Candidate Information

Job description

Department / division:	Division of Clinical Studies, ICR-CTSU
Pay grade / staff group:	Research Management 4
Hours / duration:	Part time (0.6fte) Fixed term contract for 2 years
Reports to:	ICR-CTSU Assistant Operations Director
Main purpose of the job:	Quality oversight of ICR clinical trials

Role Summary:

We would like to appoint a Quality Assurance Manager to be responsible for the design, implementation, maintenance and ongoing improvement of quality assurance systems of ICR clinical trials. The post holder will report to the ICR-CTSU Assistant Operations Director and will provide QA leadership to the joint ICR-CTSU/DDU IIT 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).

The post holder will plan, 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 provide quality assurance advice and support to colleagues within ICR-CTSU and represent ICR-CTSU at relevant meetings within the wider ICR and Royal Marsden (RM) institutions and nationally, as required. The post-holder will also work with the ICR's Drug Development Unit (DDU) to align Quality Assurance activities across ICR sponsored clinical trials.

ICR-CTSU is in the process of implementing cloud-based e-trial solutions, including eTMF, to support their trials portfolios. The post-holder will have a key role in ensuring quality processes for implementation and on-going use.

Typically, ICR-CTSU 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. This is an office based role. Requests for hybrid working (splitting time between our Sutton site and home) may be considered following successful completion of key training and if the role allows. Flexible working options may be considered.

Quality Assurance Manager
Candidate Information

Duties and responsibilities:

Quality Assurance

Take a lead role in the management and long-term strategic development of quality control and quality assurance (QA) processes
Provide QA leadership to the joint ICR-CTSU/DDU IIT Quality Assurance Review Team, managing the review of existing quality systems and procedures, identifying areas for improvement as necessary.
Develop and oversee the maintenance of the ICR-CTSU Quality Management System, including processes, policies and standard operating procedures (SOPs)
Provide quality assurance advice and training to ICR-CTSU and DDU IIT staff.
Represent ICR-CTSU 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 SOP Working Group.

Audit

Working with the Assistant Operations Director, Head of Investigator Initiated Research and Deputy Director (Operations), design, 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 and preventative actions are implemented.
Assist in the preparation for and coordination of regulatory and sponsor audits and inspections and follow up any corrective actions to ensure they are implemented within specified timeframes.

Pharmacovigilance

Plan, conduct and oversee regular quality control checks of pharmacovigilance systems to ensure PV reporting is compliant with current regulations and SOPs.
Provide QA leadership to the joint ICR-CTSU/DDU Pharmacovigilance Working Group.

Regulatory Oversight

Report on current compliance with relevant legislation, governance and good practice guidelines to the ICR-CTSU Management Group via the Deputy Director (Operations).
Provide advice/support for new Clinical Trial Applications and Amendments, to ensure accuracy of content and compliance with MHRA requirements for new trial applications.

Quality Assurance Manager
Candidate Information

Other

Line management or mentorship of more junior members of the QA team, as required
Participate in continuous professional development, keeping up-to-date with current legislation and practices and disseminate that knowledge effectively.
Oversee archiving of TMFs, in line with the current regulations and relevant SOPs.
Other duties as required that are consistent with the nature of the role.

Quality Assurance Manager
Candidate Information

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/qualification/professional membership or equivalent in quality management	Desirable

Skills

Expert knowledge of quality systems and regulatory requirements in clinical research	Essential
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 the development and management of annual audit program	Desirable
Experience of design, conduct and reporting of clinical trial 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
Experience in pharmacovigilance reporting and management	Desirable

Quality Assurance Manager
Candidate Information

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
Line management experience	Desirable

Quality Assurance Manager
Candidate Information

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

Quality Assurance Manager
Candidate Information

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

For general queries about the recruitment process, please contact ICR-CTSU, email: ctsu@icr.ac.uk.

This job description reflects the current position and is subject to review and alteration in detail and emphasis in the light of future changes or development.