Candidate information pack

Clinical Research Quality Assurance Officer

Clinical Research & Development

At The Royal Marsden, we deal with cancer every day, so we understand how valuable life is. And when people entrust their lives to us, they have the right to demand the very best. That's why the pursuit of excellence lies at the heart of everything we do.

Life demands excellence

Dear candidate

Thank you for applying to join the Joint Clinical Research & Development Core Services (Good Clinical Practice and regulatory compliance function) as Clinical Research Quality Assurance Officer. This candidate pack contains all you need to apply for the post.

The Royal Marsden has a vital role in championing change and improvement in cancer care through research and innovation, education and leading-edge practice. We are incredibly proud of our international reputation for pushing the boundaries and for our ground-breaking work ensuring our patients receive the very best and latest in cancer treatment and care.

Our cancer clinical research portfolio is both world-leading and practice changing. This is a unique opportunity to help develop, oversee and deliver an exciting portfolio and join a team dedicated to advancing clinical practice.

I wish you every success in your application.

Mark Brandon-Grove, Head of Clinical Research Performance and Quality

Key information

Job title
Clinical Research Quality Assurance Officer

Directorate
Clinical Research

Grade
Agenda for Change band 6

Contract
Permanent

Hours of work
37.5 hours

Location
The Royal Marsden has two sites – Chelsea, London and Sutton, Surrey. The post holder will be based at Sutton with a presence required in Chelsea (involving travel between sites) and home working as required and agreed with the line manager. There may be rare requirements to travel nationally and internationally to represent the service or oversee the portfolio.

Reports to
Clinical Research Senior Quality Assurance Officer

Accountable to
Clinical Research Quality Assurance Manager; Head of Clinical Research Performance and Quality; Director of Clinical Research Operations

1. Clinical research at The Royal Marsden and the Institute of Cancer Research

Every day in the UK, over 1,000 people of all ages are diagnosed with cancer. More than half will currently die from this devastating disease. Many survive with long-term effects that can reduce their quality of life. Also, cancer does not affect everyone equally. Some people and groups are more vulnerable, some are less likely to access modern medical innovations, and some are more likely to die from cancer.

The Royal Marsden NHS Foundation Trust is recognised worldwide for the quality of its cancer services and is rated outstanding by the NHS regulator. The Institute of Cancer Research (ICR) is the only UK academic institution solely devoted to the understanding of cancer. Together, we have a long history of driving research that changes NHS care and practice, tackling the inequalities and challenges of cancer.

Our shared vision is to improve outcomes for everyone at risk of and affected by cancer across the UK; through development of new approaches to prevention, more accurate and earlier diagnosis, and bespoke therapies, underpinned by smart use of data and technology.

At any time, we have more than 900 clinical research studies active, supported by an extensive workforce including a core clinical research and development team. We benefit from working with globally recognised key opinion leaders, committed researchers and research support staff, and world-class infrastructure.

The Joint Clinical Research & Development Core Services team is based in the Oak Cancer Centre in Sutton, providing a modern and welcoming working environment within a hub of innovation and discovery.
The Royal Marsden values diversity and is committed to the recruitment and retention of underrepresented minority groups. We particularly welcome applications from Black, Asian and minority ethnic candidates, LGBTQ+ candidates and candidates with disabilities.

2. What we will give you

- **Job satisfaction.** Your work will make a direct impact on people with cancer, improving and saving lives in the NHS and beyond. You will see those that benefit on a daily basis.
- **Professional development.** Your professional growth is one of our top priorities, with a wide range of internal and external courses available, including funding/support to undertake higher degrees, and the option to attend national conferences. *(Correct at time of candidate information pack preparation).*
- **Flexibility.** We embrace different perspectives, work styles, health and wellness approaches, care of families and productivity.
- **Outstanding facilities.** The core clinical research and development team is based in the Oak Cancer Centre in Sutton, a new £70M investment providing a modern and welcoming working environment within a hub of innovation and discovery. *(Correct at time of candidate information pack preparation).*
- **Benefits package.** Our generous holiday entitlement is 27 days per year, rising to 29 days after five years' service and 33 days after 10 years' service, plus bank holidays. You will be automatically enrolled to the NHS pension scheme, widely acknowledged as one of the best pension schemes available. As an NHS employee you can subscribe to a number of benefits/services and save money with hundreds of discounts at retailers locally and nationally. *(Correct at time of candidate information pack preparation).*
- **Psychological safety.** We support an environment of fearlessness to push the boundaries of cancer research. We want you to share your ideas, speak candidly and take data-informed risks to help push the boundaries.
- **Commitment to diversity**. We strive to foster a welcoming workplace where everyone can thrive.

3. Overview of the post.

The Clinical Research Quality Assurance Officer is member of the GCP and regulatory compliance function, sitting within the Joint Clinical Research & Development Core Services. The purpose of the role is to support quality and compliance across the clinical research portfolio, at both The Royal Marsden and the Institute of Cancer Research (ICR).

This role will support the Clinical Research Senior Quality Assurance Officer and the Clinical Research Quality Assurance Manager in developing and maintaining the Quality Management System (QMS) across The Royal Marsden and the ICR.

This role is to provide digital systems oversight and management (the post holder will be expected to act as primary point of contact and escalation for Electra, our electronic trial master file / investigator site file solution, and other digital systems including DocuSign), support in coordinating risk management, (potential) serious breach management, and monitoring effectiveness of Corrective and Preventative Actions (CAPA) implementation and quality improvement initiatives.

The post-holder will support audit activities, delivering audits as part of the annual audit programme as required. They will also contribute to the quality-by-design programme by contributing to protocol development.

4. Main duties and responsibilities

4.1 Quality Management System oversight

- Support the writing of SOPs and guidance documents, and the development of templates and forms that ensure the implementation of GCP and relevant regulations.
- Coordinate and manage the suite of research SOPs, ensuring that reviews are undertaken in a timely manner with wide representation.
- Facilitate the activities of the RM/ICR Standard Operating Procedures Working Group (SOP-WG) and Standard Operating Procedure Oversight Group (SOP-OG).

4.2 (Potential) serious breach management

- Handling of (potential) serious breaches of the clinical trials regulations and/or GCP, and to take forward notification of such breaches to regulatory authorities in accordance with regulatory requirements.
- Support with serious breach management and CAPA effectiveness implementation and audit.

4.3 Risk management and quality improvement

- Facilitate the activities of the RM/ICR Risk Identification Group (RIG).
- Coordinate input and update of the Joint Research Active Risk Log, ensuring that risk description, control and rating are reviewed with wide representation.
- Ensure concordance of the Joint Research Active Risk Log pertinent to clinical research with the institutional risk logs of RM and ICR.
- Specialise in quality improvements of clinical trial conduct by supporting research delivery and management teams to identify process and systematic issues. To work with teams to establish better processes and procedures to meet with regulatory standards and legislation.
- Participate in other relevant quality assurance initiatives and processes in clinical trials.
- Identify gaps in process and take steps to address these as appropriate – including developing and delivering training and communication materials (e.g. bulletins, presentations, posters, etc.).
- To assist with monitoring and supporting DATIX incident reporting including reviewing and investigating incidents.

4.4 Quality-by-design

- Co-review new and amended research protocols and essential documentation as part of sponsor oversight prior to submission for regulatory approval.

4.5 Regulatory inspections

- In the event of an MHRA or other regulatory inspection, help to prepare dossier/pre-inspection paperwork, provide training, support research units and facilitate the inspection as directed by Clinical Research Quality Assurance Manager.
- Assist with other external audits/inspections.

4.6 Training delivery

- To support and deliver ad-hoc and scheduled GCP practical aspects of training to research units.

4.7 Supporting the audit programme if required

- Take part in the delivery of audits to support the audit function as required.
- Support the implementation of corrective and preventative actions (CAPAs) for findings from clinical trial audits.
- Facilitate meetings with research team members where necessary to ensure findings are communicated appropriately.
- Support teams with external audit and inspection, and document outcomes.

4.8 Digital systems management

- Act as primary point of contact, administration, support and escalation for Electra (our electronic trial master file / investigator site file solution) and DocuSign (our eSignature provider), rapidly providing support and troubleshooting issues.
- Develop expert knowledge of Electra and DocuSign.
- Support delivery of the Electra optimisation group for system development.
- Liaise with the manufacturer of Electra and DocuSign to ensure system upgrades.
- Oversee and ensure Electra and DocuSign is fully integrated into business-as-usual activity across clinical research.
- Manage the Electra mailbox, supporting, maintaining and managing user access.
- Support the implementation of new digital systems as required.

4.9 Miscellaneous

- Ensure the views of both The Royal Marsden and the ICR are represented.
- Respond to difficult situations in a positive manner, using excellent problem-solving skills.
- Actively participate in and contribute to team meetings.
- Support ongoing service development, suggesting ways of improving own and departmental working practices.
- Act as a contact point for queries relating to research governance and GCP from staff involved with research at all levels across RM/ICR.
- To assist with monitoring and replying to GCP Compliance Team inbox queries.
- To attend conferences and workshops related to new laws and new information relevant to the post. This may require overnight stays.
- Contribute to supportive, can-do culture that promotes equality, diversity and inclusivity in all that we do.
- Be responsible for maintaining own professional development and be aware of current practices and future developments within The Royal Marsden and the ICR.
- Participate in any training and personal development as self-identified or identified by the post's line manager.
- Contribute to supportive, can-do culture that promotes equality, diversity and inclusivity in all that we do.
- Undertake any other duties that may be required, including supporting the clinical service activity of The Royal Marsden as required (work in other departments during times of extreme staff shortage or increased workload to ensure that the Trust provides a continued service).

5. Confidentiality and data protection

All employees of The Royal Marsden NHS Foundation Trust must not, without prior permission, disclose any information regarding patients or staff (please also see the Trust's policy on Whistleblowing). In instances where it is known that a member of staff has communicated information to unauthorised persons, those staff will be liable to dismissal. Moreover, the Data Protection Act 2018 also renders an individual liable for prosecution in the event of unauthorised disclosure of information.

6. General Data Protection Regulation

You will familiarise yourself with the Trust's data protection policy which sets out its obligations under the General Data Protection Regulation and all other data protection legislation. You must comply with the Trust's data protection policy at all times and you agree that you will only access the systems, databases or networks to which you have been given authorisation. The Trust will consider a breach of its data protection policy by you to be a disciplinary matter which may lead to disciplinary action up to and including summary dismissal. You should also be aware that you could be criminally liable if you disclose personal data outside the Trust's policies and procedures. If you have any queries about your responsibilities in respect of data protection you should contact the Trust's Data Protection Officer.

7. Safeguarding children and vulnerable adults

All staff must be familiar with and adhere to the Trust's child protection and safeguarding adult policies and procedures. All staff are required to attend child protection and safeguarding adults awareness training, additional training and supervision regarding child protection relevant to their position and role.

8. Health and safety

All staff are required to make positive efforts to maintain their own personal safety and that of others by taking reasonable care, carrying out requirements of the law whilst following recognised codes of practice and Trust policies on health and safety.

9. Customer service excellence

All staff are required to support the Trust's commitment to developing and delivering excellent customer-focused service by treating patients, their families, friends, carers and staff with professionalism, respect and dignity.

10. Emergency planning

In accordance with the Trust's responsibilities under the Civil Contingencies Act 2004 all staff are required to undertake work and alternative duties as reasonably directed at variable locations in the event of and for the duration of a significant internal incident, major incident or pandemic.

11. Equality and diversity policy

The Royal Marsden NHS Foundation Trust is committed to eliminating all forms of discrimination on the grounds of age, disability, gender reassignment, marriage / civil partnership, pregnancy / maternity, race, religion or belief, sex and sexual orientation.

12. No smoking policy

It is the policy of the Trust to promote health. Smoking is actively discouraged and is prohibited in most areas of the Hospital, including offices, with the exception of designated smoking areas on both sites.

13. Review of this job description

This job description is intended as an outline of the general areas of activity. It will be amended in the light of the changing needs of the organization, in which case it will be reviewed in conjunction with the post holder.

14. Terms and conditions of employment

This post is exempt from the Rehabilitation of Offenders Act 1974, meaning that any criminal conviction must be made known at the time of application.

15. Flu Vaccination- What we expect from our staff

At The Royal Marsden we have an immune compromised patient population who we must protect as much as we can against the flu virus. Each year, seasonal flu affects thousands of people in the UK. Occurring mainly in winter, it is an infectious respiratory disease capable of producing symptoms ranging from those similar to a common cold, through to very severe or even fatal disease.

The wellbeing of our staff and patients is of the upmost importance to us, and it is the expectation of The Royal Marsden that all patient-facing staff have an annual flu vaccination, provided free of charge by the Trust.

16. Person specification

These requirements will be used to shortlist candidates, so please use the supporting statement section on the application form to detail how you meet these requirements.

Candidates must be able to demonstrate	Essential or Desirable	Assessed by
Education/Qualifications		
• A levels (or equivalent) • Recognised GCP training	Essential	Application form / Interview
• Educated to degree level or equivalent experience in clinical research	Desirable	Application form / Interview
Experience		
• Experience of working in the NHS or relevant clinical / research environment in a regulatory compliance role • Experience of working across organisational boundaries with multidisciplinary teams • Experience of working with GCP and clinical research regulations • Experience of digital system management	Essential	Application form / interview
• Experience of working with non-commercial clinical research	Desirable	Application form / interview
Skills Abilities/knowledge		
• Ability to read and understand clinical research protocols • Ability to summarise and explain complex issues to both technical and non-technical audiences • Excellent administrative and organisational skills • Proficient in the using PC based Windows and Microsoft Office software including Access & PowerPoint • Ability to work in a proactive manner to identify new risks and issues and flag upwards appropriately • Ability to work well within a multi-disciplinary team environment • Able to work under pressure, methodical in approach, with effective problem-solving ability • A high level of accuracy and attention to detail • Ability to work on own initiative • Proven ability to organise own work in busy work environment and time critical situations	Essential	Application Form / Interview
Other Requirements		
• Flexible to meet the needs of the service (e.g., working ad hoc to support regulatory inspections) • Able to work on both sites and to be flexible to meet the needs of the role	Essential	Application Form / Interview