Candidate information pack

Senior Trial Manager

Lung Clinical Research Unit

NHS

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 Lerner Lung & Mesothelioma Research Unit at The Royal Marsden. 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.

Thank you for your interest in working for The Royal Marsden, I wish you every success in your application.

Sincerely,

Zahara Ghory

Research Operations Manager

Job title

Senior Clinical Trial Manager

Directorate

Clinical Research

Grade

Agenda for Change Band 7

Contract

Fixed term (1 year)

Hours of work

37.5 hours per week

Location

The Royal Marsden has two sites - Chelsea, London and Sutton, Surrey. The post holder will be expected to work flexibly across both sites as required and agreed with their line manager

Reports to

Senior Trial Manager / Operations Manager

Accountable to

Clinical Unit Research Lead

Divisional Director, Clinical Research

Liaises with

Research Staff, Clinical Research and Development Staff, Support Services within the Trust, Pharmaceutical Company Staff, other Sponsors and Funders of clinical research, Auditors / Monitors / Regulatory Inspectors, Clinical Committee for Research

1. The Royal Marsden

The Royal Marsden is recognised worldwide for the quality of its cancer services. The Trust's strategic aim is to achieve excellence in cancer treatment and diagnosis, through partnership and collaboration.

The prime purpose of the Trust is the provision of state-of-the-art cancer services as well as enabling research into the development of improved methods of prevention, diagnosis and treatment of cancer. Its other main purpose is teaching and the dissemination of knowledge both nationally and internationally. In 1991 it became the first NHS hospital to be awarded the Queen's Award for Technology for its work on drug development. The hospital gained National Charter Mark Awards in 1995, 1998, 2001, and again in 2008 for the excellence of its services and achieved the international quality standard ISO 9001 for radiotherapy in 1996 and for chemotherapy in 2003. The Royal Marsden has consistently been awarded three stars and more recently double excellent rating in the NHS performance indicators, rating it among the nation's best in terms of clinical quality and patient care.

The Royal Marsden comprises two sites at Chelsea and Sutton and over 40,000 patients attend the Royal Marsden each year. The Trust employs 3600 staff, including 335 medical staff. As a specialist cancer centre, the Trust serves local populations within the London Boroughs of Merton, Sutton, Wandsworth, Kensington & Chelsea and Westminster, as well as receiving referrals both nationally and internationally.

2. Overview of the Post

- To take responsibility for ensuring assigned portfolio of clinical trials within the Unit are conducted and managed in accordance with Good Clinical Practice and Trust SOPs and trial protocols.
- To be responsible for managing both RMH/ICR Sponsored and Hosted studies within the Unit.
- To be responsible for conveying the requirements of the Clinical R&D Office to clinical staff within their allocated Clinical Unit.
- To provide an efficient clinical trial coordination service to the Unit Head, ensuring trials fulfil all statutory requirements.
- To oversee the conduct of assigned portfolio of trials within the Unit and maintain day to day responsibility for specific trials within the Unit.
- To represent the Unit at key meetings and deputise for the Operations Manager as required.

3. Key areas of responsibility

These responsibilities will be carried out under the guidance of the Operations Manager.

Service Delivery

- Contribute to the Unit development and strategy.
- Under the direction of the Operations Manager to lead implementation of systems within the Unit to ensure all Clinical Trials are conducted in accordance with all regulatory internal requirements including:
    a. Medicines for Human Use (Clinical Trials) Regulations
    b. Research Governance Framework for Health and Social Care
    c. Human Tissue Act
    d. Research and Development Policies and SOPs
- To be the main point of contact for the clinical R&D Office for set up and management of an assigned portfolio of clinical trials.

- To coordinate the Unit's portfolio meeting as appropriate, ensuring documented monitoring of the clinical trial portfolio.
- To be a member of Trust Forums as appropriate.
- To facilitate monitoring and audit of clinical trials by internal and external Clinical Trial Monitors and Auditors and to coordinate the research teams' response to audit findings.
- To lead implementation of corrective and preventative measures within the Unit as agreed with the Operations Manager and Unit Head.
- To support the Clinical R&D Office in preparation for regulatory Inspections.
- To establish and maintain good channels of communication within the clinical research team, with other departments within the Trust and with other relevant organisations including non-commercial bodies and pharmaceutical sponsors.
    a. Ensure assigned trial portfolio within the Unit are audit/inspection ready at all times.

Clinical research management

- Responsible for essential trial documentation compilation and maintenance of Trial Site/Master Files.
- Liaise with relevant department to ensure appropriate agreements are in place for trials involving transfer or receipt of tissue/data.
- Responsible for ensuring assigned trials within the Unit's Clinical Research Portfolio are conducted in accordance with GCP, all regulatory requirements and SOPs.
- To review capacity and resource requirements within the Clinical Unit for coordination and administrative management of trial portfolio and to advise the Operations Manager and Unit Head accordingly.
- To be the main point of contact for assigned trials to both external and internal stakeholders.
- As a member of the multi-disciplinary team ensure recruitment of patient to a trial is carried out appropriately, including ensuring informed consent, screening, randomisation and safety reporting processes are followed as per protocol and notify the clinical team of any discrepancies.
- Ensure timely raising and payment of invoices for externally funded clinical trials.
- To ensure trial closure is notified to Clinical R&D Office, Sponsor, REC and MHRA as appropriate.
- To ensure appropriate archiving of trial documentation and be the Unit's dedicated archivist for clinical trial records.

RMH/ICR Sponsored Studies

- Complete applications and amendments to Sponsor, REC, and MHRA for new research proposals.
- Organising regular meetings as needed to facilitate the efficient management of the clinical trial, including preparing the agenda and meeting papers and writing minutes.
- Preparation of and continual update of essential trial documentation in collaboration with the CI, Clinical Fellow (where relevant), Clinical Trial Database Programmer and Statistician.
- To be the main point of contact for participating sites in multi centre studies ensuring appropriate assessment of site feasibility for trial participation, planning site initiation visits and ensure sites have all applicable documentation in place.
- To have oversight of clinical trial activity and conduct of designated clinical trials.
- Manage systems for tracking trial conduct, such as ensuring recruitment and data entry targets are met and checking stock of IMP at sites.
- Draft regular progress reports to REC, Clinical R&D Office, funders, sponsors and regulatory bodies as appropriate.
- Conduct source data verification and monitoring as required at participating sites across UK and globally where appropriate.

- Contribute to the design and validation of the clinical study database together with the Research Team, Database Programmer and Statistician.
- Conduct timely and efficient procedures for the collection, review and verification of all patient data.
- Assist with data cleaning before SRCs/Interim analysis.

Management and Leadership Responsibility – including human resources, financial and other resources

All posts with responsibility for managing staff are expected to lead, motivate, develop and reward staff and are required to comply with the Trust's policies and Manager's Code of Conduct.

- Line Management of Junior staff where applicable and as delegated by the Operations Manager.
- Responsible for the effective recruitment and selection of staff in line with the Trust's Recruitment Code and Recruitment & Selection Processes and Standards as delegated by the Operations Manager.

General responsibility

- To be responsible for maintaining own professional development and be aware of current practices and future developments within the Trust and National Health Service.
- To aid in the implementation of corrective and preventative measures within the Unit as agreed with the Unit Head.
- To support the Clinical R&D Office in preparation for regulatory inspections.
- To take an active role in the Unit and the Trust as a member of a clinical research team.
- To help coordinate the Unit's research meeting ensuring appropriate, documented monitoring of the clinical trial portfolio.
- Any other duties that may be required that are consistent with the nature of the grade of the post.

4. 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 1998 also renders an individual liable for prosecution in the event of unauthorised disclosure of information.

5. 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.

6. 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.

7. 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.

8. 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.

9. 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.

10. 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.

11. 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.

12. 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.

13. 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.

14. 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.

15. Person Specification

Candidates must be able to demonstrate	Essential or Desirable	Assessed by
Education/Qualifications		
Masters' Degree or other higher-level degree in Life Sciences or relevant experience	Essential	Application form / Interview
Recent GCP training	Essential	Application form / Interview
Experience		
Significant experience of working in a clinical trial setting	Essential	Application form / Interview/References
Detailed understanding and experience of clinical trials, UK Clinical trial regulations, GCP and regulatory framework	Essential	Application form / Interview/References
Experience of trial finances including costing for academic and commercial studies	Essential	Application form / Interview/References
Personnel leadership and management experience	Desirable	Application form / Interview/References
Skills & Knowledge		
Advanced organisational skills and ability to manage multiple projects at various stages of development and organisation	Essential	Application form / Interview/References
Excellent communication skills and ability to facilitate collaborative working relationships	Essential	Application form / Interview/References
Able to work under pressure, methodical in approach, with effective problem-solving ability	Essential	Application form / Interview/References
Competence in research orientated PC software including Microsoft Office packages	Essential	Application form / Interview/References
Knowledge of principles for quality management systems	Desirable	Application form / Interview
Knowledge of budget planning and management	Desirable	Application form / Interview
Other Requirements		
Able to work on both sites and to be flexible to meet the needs of the role	Essential	Application/Interview
Willingness to travel within the UK and occasionally overseas to attend meetings and conferences	Desirable	Interview

The above attributes have been identified to be necessary for this post and will be used when short listing candidates.