The ROYAL MARSDEN
NHS Foundation Trust

Candidate information pack

Lead Project Manager

GI & Lymphoma RM Clinical Trials 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 Royal Marsden Clinical Trials Unit (RM CTU) GI & Lymphoma unit , a sub-team of our UKCRC registered CTU. 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 sponsored GI/Lymphoma 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 team dedicated to advancing clinical practice in GI/Lymphoma cancer.

I wish you every success in your application.

Debra Townsend-Thorn, The Head of Clinical Trial Management

Key information

Job title

Lead Project Manager – GI & Lymphoma Unit RM CTU

Directorate

Royal Marsden Clinical Trials Unit (RM CTU) GI & Lymphoma Cancer Portfolio, within the Clinical Research Directorate

Grade

Agenda for Change band 7/8a

Contract

Permanent

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 based at Sutton with regular travel between sites.

Reports to

Head of Clinical Trial Management

Accountable to

Director and Assistant Director of Clinical 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 (87 inpatient beds and an 8 bedded day unit at Chelsea and 128 beds at Sutton including paediatrics). 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. RM CTU and the GI & Lymphoma Cancer Portfolio

RM CTU is a UKCRC accredited clinical trials unit, with a wide-ranging portfolio of cancer research trials across multiple tumour groups. Our UKCRC accreditation indicates RM CTU as a centre of excellence with a strong track record of coordinating multi-centre trials, expert staff to develop studies, robust quality assurance systems and evidence of long-term viability of capacity for trial management. Our unique feature among CTUs is that our trial management expertise is aligned with and integrated with our clinical knowledge and expertise at The Royal Marsden.

The GI/lymphoma unit has an international track record in devising and delivering internationally practice changing and impactful research. The unit has a large portfolio of both academic and commercial clinical studies, The Lead Project Manager will be working on the large, sponsored portfolio consisting of academic CTIMPS and tissue studies, both single centred and multicentred.

3. Key researchers affiliated with the Portfolio

The Chief Investigators affiliated with the portfolio are world-leading clinical researchers with a track record of practice-changing clinical trials:

Head of Unit

- Professor David Cunningham

Consultants (medical oncology)

- Professor David Cunningham (also Medical Oncology Training Programme Director & Director of Clinical Research)

- Professor Ian Chau (also GI/lymphoma Unit Research Lead)
- Dr Naureen Starling (also NIHR BRC Training Lead & Associate Director of Clinical Research)
- Dr Sheela Rao
- Dr Charlotte Fribbens
- Dr Zohra Ali
- Dr Avani Athauda
- Dr Shelize Khakoo
- Dr Hazel Lote

4. Overview of the post

This post is responsible for the development, oversight and delivery of the GI/Lymphoma portfolio managed within RM CTU.

There are three key domains to the post - project management, team management and portfolio management; in addition to corporate contribution.

This position will be offered at the 8a grade if sufficient experience is shown in the application and interview.

We would also like to invite experienced trial managers, who would like to progress. We would work closely with the trial manager to ensure experience is gained through a preceptorship period (1 year), progressing them from a Band 7 to a Band 8a Lead Project Manager. There will be set criteria discussed at the start of the role to aid the transition from a band 7 to a band 8a

The post-holder will project manage a number of complex Medicines and Healthcare products Regulatory Agency (MHRA) regulated clinical trials, ensuring that they are set-up, delivered, and closed-down in accordance with Good Clinical Practice (GCP) and all applicable regulations. The post therefore requires a clinical research professional with excellent project management skills and extensive experience of sponsor-level management of clinical trials in an academic environment.

The post-holder will establish, develop and manage a growing team of senior trial managers and data managers, each of which will work on their own portfolio of sponsored studies. The post will oversee the line management of these staff and prioritise and allocation workload to ensure effective and efficient trial management and delivery.

The post-holder will have oversight of the GI/Lymphoma cancer portfolio, providing leadership and vision for the portfolio and working closely with the key researchers acting as Chief Investigator on the individual trials. This portfolio includes the sponsor-level management of both Medicines and Healthcare products Regulatory Agency (MHRA) and Human Tissue Authority (HTA) regulated research. This will require management and oversight of finances, and the development and adoption of standardised processes to achieve optimal efficiency in the portfolio.

Additionally, roles within RM CTU have a corporate contribution requirement, in which the post-holders work collaboratively across the Clinical Research Directorate, enabling a supportive culture of excellence by contributing training and service improvement programmes. All roles are also expected to prioritise professional development, maintaining cutting-edge skills and expert knowledge.

5. Main duties and responsibilities

Project management

Trial set-up and initiation

- Comprehensive knowledge and experience of setting up and running academic CTIMP studies, both single centred and multi centred.
- Coordinate the set-up and management of clinical trials in the GI/Lymphoma cancer portfolio.
- Contribute to clinical trial design, protocol development and funding applications together with Chief Investigator (CI), statistician and other members of the team.
- Input into clinical trial protocols, prepare funding applications for new study proposals and prepare clinical trial budgets.
- Contribute to preparation of essential clinical trials documents, including protocol, patient information sheets in collaboration with the CI, clinical fellows etc.
- Contribute to preparation of trial documentation e.g. trial guidance notes, case report forms (CRFs), monitoring plans, in collaboration with relevant members of the trial management team including the CI, clinical fellow (where relevant), monitor, database programmer and statistician.
- Contribute to preparation and submission of applications for ethics, regulatory, sponsor, and other approvals that may be required in order to conduct the clinical trial.
- Ensure all the required approvals and agreements are in place before the trial opens to recruitment.
- Ensure clinical supplies or equipment are available and distributed appropriately.
- Set-up the Trial Master File (TMF) and support research sites in the setup and maintenance of Investigator Site Files (ISF).
- Coordinate set-up of trial oversight committees and charters in collaboration with CI, statistician and other members of the team.
- Plan and perform site initiation visits ensuring sites have all applicable documentation in place and that Principle Investigators (PIs) and site staff understand the protocol and their responsibilities within the trial.

Trial management

- Liaise closely with the CI, database programmer, statistician and other key members of the study team (i.e. clinical fellow) to ensure on-going clinical, scientific and operational oversight.
- Be a point of contact for participating sites, sponsor(s), funder(s), pharmaceutical partners, regulatory authorities and the trial oversight committees.
- Oversee the day-to-day conduct of the study at participating sites, providing support and advice and addressing any logistical issues as they arise.
- Organise regular meetings as needed to facilitate the efficient management of the clinical trial, preparing the agenda and meeting papers, and provide minutes following the meeting in a timely manner.
- Ensure timely data collection and receipt / transfer of any clinical materials or samples for clinical trials.

- Maintain quality control procedures for all aspects of trial conduct to ensure compliance with the principles of GCP, research governance standards and all applicable legislation (e.g. The Medicines for Human Use (Clinical Trials) Regulations, Data Protection Act, Good Clinical Laboratory Practice, Human Tissue Act /Human Tissue Bill (Scotland).
- Develop and manage systems for tracking trial conduct, such as ensuring recruitment and data entry targets are met and establish procedures for dealing with problems arising from any shortfall in performance with trial team.
- Update trial documentation as necessary e.g. protocols, trial guidance notes, CRFs and patient information sheets.
- Prepare and submit amendments as appropriate to ethics, regulatory, etc, in collaboration with relevant members of the trial team.
- Prepare regular progress and safety reports e.g. to funding bodies, ethics, regulatory, TMG meetings.
- Maintain the TMF to ensure a clear audit trail of trial activities is retained.
- Liaise with other members of the trials teams to ensure the smooth running of all clinical trials at every stage of the clinical trials process.
- Manage the close-down of a clinical trial or research project including preparation of all necessary documentation for ethics, regulatory and sponsor.
- Arrange for archiving of all essential documents following trial close-down

Data management

- Contribute to the design and validation of the clinical study database together with the database programmer and statistician.
- Implement and oversee timely and efficient procedures for the collection, and verification of all patient data.
- Coordinate record management systems for all trial material.
- Coordinate up to date trial guidance notes for participating sites.
- Coordinate team to ensure trial procedures are being followed and to promote the reporting of high quality data.

Clinical trial monitoring / safety reporting

- Receive SAEs and co-ordinate review and reporting safety information eg SAEs, SUSARs and DSURs according to established sponsor and regulatory procedures
- Oversee or perform on site monitoring visits or remote monitoring at participating sites (as appropriate for the trial) to verify trial activities are compliant with the trial protocol, GCP and all applicable regulations.
- Contribute to preparation of data for DMC, interim and/or full analysis in collaboration with the database programmer and statistician.
- Coordinate preparation and submission of annual progress and safety reports and end of trial reports.

Team management

- Line manage trial team members including senior trial managers and data managers where required, conducting annual appraisals to set objectives, review progress against objectives and identify areas for development.
- Prioritise and allocate workloads within the trial team to ensure all trials are supported effectively and efficiently.
- Report to the Clinical Research Operational Manager on a regular basis to inform them of current and planned workloads to enable review of capacity within the team.
- Ensure cover is in place for periods of absence.

Portfolio management

- To develop project management plans for RM CTU GI/Lymphoma cancer portfolio trials to ensure active management to time and target.
- To hold regular review meetings of the portfolio and monitor progress against plan.
- To identify barriers to set up and delivery of trials and recommend actions, escalating to the Clinical Research Operations Manager or Assistant Director of Clinical Research where appropriate.
- To review capacity within the RM CTU GI/Lymphoma cancer portfolio team and make recommendations on resource /capacity requirements to ensure delivery of the portfolio.
- To be a point of contact for researchers wishing to conduct trials with RM CTU GI/Lymphoma cancer portfolio trials team.
- To report on trial performance.
- Produce a regular update report on the progress of all studies open or in feasibility, identifying risks and including mitigation plans as required in conjunction with the senior trial managers.

Finances

- To work with researchers to ensure full costing of clinical research to be managed by RM CTU GI/Lymphoma cancer portfolio team, using expert knowledge of AcoRD categorisation and attribution.
- To oversee the financial management of the RM CTU GI/Lymphoma cancer portfolio, ensuring financial flows into and out of the portfolio budget in an efficient and timely manner.
- Ensure the financial viability of the portfolio and team tasked with managing it.

Audit/Inspection

- Assist in the preparation for audits or statutory inspection by the MHRA or any other body and assist in the implementation of any corrective plans.
- Facilitate any audit, inspection or progress visit processes required by regulatory bodies, or sponsor(s).

Policy and process development

- Contribute to development and review of RM-CTU SOPs, policies and processes, and take responsibility for proposing necessary changes or additions to ensure legal and regulatory compliance and contribute to process improvement; communicate any changes to those affected by them, which will include researchers.
- Develop and update standard working practices for senior trial managers and data managers.

Communication / relationships

- Build strong relationships and have direct communication with other members of the research team to ensure the smooth running of a clinical trial or research project during its life cycle.
- Communicate with external stakeholders, e.g. ethics committees, universities and other R&D departments.
- First point of contact for queries on assigned studies including hospital site personnel (i.e. clinicians, nurses, data managers).
- Contribute to /arrange the planning and organisation of trial meeting as appropriate for the trial including investigators/ research nurses/trial coordinators.
- Contribute to the preparation of abstracts, posters and manuscripts.

Corporate contribution

- Contribute to updating and developing skills by delivering and instigating appropriate training across The Royal Marsden in clinical trial management, methodology and coordination, including all regulations relevant to clinical trial conduct.
- Participate in relevant meetings including study specific, role specific and wider team meetings as required with responsibility for taking and distributing minutes if required.
- Be an expert on the regulatory requirements for conducting clinical trials.
- Act as a champion of RM CTU and The Royal Marsden, and represent at national and international meetings and conferences as required.
- Contribute to supportive, can-do culture.
- Develop an understanding of GI & Lymphoma cancer.

6. 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.

7. 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.

8. 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.

9. 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.

10. 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.

11. 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.

12. 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.

13. 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.

14. 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.

15. 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.

16. Person specification

Education/Qualifications	Measurement
Essential • Educated to degree level (e.g. BA or BSc) or equivalent experience • Good Clinical Practice certification **Desirable** • Higher degree qualification (e.g. MSc) in a relevant subject, preferably in the medical or biological sciences. • Project management qualification (eg PRINCE 2).	Application form and interview

Experience	
Essential • Extensive experience of the sponsor-level management of MHRA and HTA regulated clinical trials in an academic environment. • Experience of safety reporting to regulatory authorities. • Experience of establishing, developing and managing a team. • Experience of working across organisational boundaries with multidisciplinary teams • Experience of developing systems and processes to allow efficient management and conduct of multi-centre clinical trials • Experience of communicating effectively with all levels of staff - written and verbal **Desirable** • Experience of developing and implementing new SOPs and processes. • Experience of MHRA inspection.	Application form, interview and references
Skills / knowledge	
Essential • Detailed knowledge of UK clinical trial regulations, GCP and regulatory frameworks. • Knowledge of developing budgets for clinical trials and practical use of AcoRD • A detailed understanding of the clinical trials approval process to conduct clinical research in the UK • Knowledge of the requirements of clinical trials and clinical research projects during their life-cycle especially at the start-up stage • Proven problem solving skills. • Excellent presentation skills • Knowledge of clinical trial design issues in conducting oncology studies. • Proficient in the using PC based Windows and Microsoft Office software including the internet and e-mail. **Desirable** • Detailed knowledge of database set-up and data management processes and procedures necessary to conduct clinical trials. • Detailed knowledge of clinical trial methodology and /or statistical issues as they pertain to clinical trials. • Excellent report writing skills. • Knowledge of Visio and or MS Project.	Application form, interview and references

Other requirements	
<u>Essential</u> • Ability to work in a proactive manner to identify new risks and issues and flag upwards appropriately. • Maintain a positive and enthusiastic attitude towards tasks and their goals. • Ability to work well within a multi-disciplinary team environment in an effective and supportive way. • Able to work under pressure, methodical in approach, with effective problem-solving ability • Ability to work effectively to tight deadlines under direction and on own initiative. • A high level of accuracy and attention to detail • Ability to prioritise workload of others while balancing own workload(s). • Flexible attitude and capable of dealing with changing working conditions. • Able to work on both sites and to be flexible to meet the needs of the role • **<u>Desirable</u>** • Clear understanding of and interest in GI & Lymphoma cancer research. • Ability to negotiate, acting in a tactful and confident manner to achieve the desired results. • Willing and able to coach and train others.	Application form, interview and references