The ROYAL MARSDEN
NHS Foundation Trust

THE ROYAL MARSDEN NHS FOUNDATION TRUST
JOB DESCRIPTION
SENIOR TRIAL MANAGER

Job Title:	Senior Trial Manager
Grade:	Band 7
Hours of work:	37.5
Location:	Chelsea
Reports to:	Clinical Research Operations Manager
Accountable To:	Assistant Director of Clinical Research

Background
The Royal Marsden NHS Foundation Trust (RM) is recognised world-wide for the quality of its cancer services. The Royal Marsden and its academic partner, The Institute of Cancer Research (ICR) have a joint research strategy which sets out to maintain and strengthen this unique partnership in order to enhance cancer research.

The Royal Marsden (RM) has a history of conducting single and multi centre clinical trials and has a large portfolio of trials, both active and in follow up. Our aim is to create a Royal Marsden-branded Perioperative Medicine & Surgical collaboration benefitting from cross-speciality resource utilisation and development of critical research infrastructure. We aim to integrate the aims of NIHR BRC Surgical Strategy into Unit research themes and develop NIHR-portfolio studies. Our Research Team will allow anaesthetists and surgeons to develop their ideas with appropriate scientific input from the unit steering committee to help develop robust trial methodology.

Overview of the Post
The Senior Trial Manager will coordinate multifunctional team(s) consisting of clinician(s), surgeon(s), statistician(s), database programmer; data manager/clinical trial assistant to project manage one or more complex clinical trials throughout their lifecycle. This may include protocol development, study set-up (including regulatory approvals), on-going study management/oversight. Working with experienced clinical trial support service staff, the post holder will ensure that all clinical trials are conducted to the relevant clinical trial regulations. In addition the Senior Trial Manager will have line management responsibilities for the Clinical Trial administrator.

The role requires a clinical research professional who has extensive experience in clinical trials conduct ideally in different settings (Pharma, Surgical, Academic) and familiarity with the regulatory environment surrounding clinical trials and the implementation of a quality management system as it pertains to clinical trial conduct.

The post holder will be based at our Chelsea site with occasional travel to Sutton.

Main Duties and Responsibilities
Trial set-up and initiation
- Coordinate the set-up and conduct of clinical trials and clinical research projects.

- Contribute to clinical trial design, protocol development and funding applications together with 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 Chief Investigator (CI), Clinical Research Operations Manager, 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) Clinical Trial Database Programmer (CTDP) 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 trial specific procedures including monitoring plans in accordance with SOPs to ensure the efficient management of the trial
- Set-up the Trial Master File and support research sites in the setup and maintenance of Investigator Site Files.
- 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 principal investigators and site staff understand the protocol and their responsibilities within the trial

Trial Management

In conjunction with the Trial Managers:-

- Liaise closely with the CI, Statistician and other key members of the study team (i.e. clinical fellow) to ensure on-going clinical, scientific and operational oversight.
- Be the principal 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 Good Clinical Practice, 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, case report forms (CRFs) and patient information sheets.
- Prepare and submit amendments as appropriate to REC, MHRA etc in collaboration with relevant members of the trial team.
- Prepare regular progress and safety reports e.g. to funding bodies, REC, MHRA, the TMG meetings.
- Maintain the Trial Master File 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 REC, MHRA and R&D.
- Arrange for archiving of all essential documents following trial close-down
- Produce regular progress reports and issue mitigation plans for Clinical Research Executive

Data management

- Contribute to the design and validation of the clinical study database together with CTDP and trial 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

- Receive SAEs and co-ordinate review and reporting safety information eg SAEs, SUSARs and DSURs according to established RM and regulatory procedures
- Ensure 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 CTDP and statistician.
- Coordinate preparation and submission of annual progress and safety reports and end of trial reports

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 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.

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.

Staff management

- Line manage trial team members, 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 the trial is supported effectively and efficiently.

Other

- Update and develop personal skills 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..

Education and Development Responsibility

- Be an expert on the regulatory requirements for conducting clinical trials.
- Be responsible for organising training for projects that they manage.
- Be responsible for ensuring that effective change management of processes if relevant to the project that they manage.

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LONDON & SURREY
PERSON SPECIFICATION

SENIOR TRIAL MANAGER

Education/Qualifications	**How measured** *(application form, interview, test, presentation, references, occupational health)*
Essential • Educated to degree level or equivalent experience **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 & Interview
Experience	
Essential • Experience of working to UK clinical trials regulations • Previous clinical trial project management experience from protocol development to reporting and archiving • Experience of working in a clinical research environment within NHS, University or pharmaceutical industry • Experience of preparing REC submissions • Experience of developing systems and processes to allow efficient management and conduct of multi-centre clinical trials • Experience of working across organisational boundaries with multidisciplinary teams • Experience of communicating effectively with all levels of staff - written and verbal • Clear understanding of and interest in cancer research • Proven problem solving skills. • Excellent presentation skills **Desirable** • Experience of developing and implementing new SOPs and processes • Experience of preparing MHRA, IRMA and other submissions • Experience of conducting complex clinical trials with IMP • Experience of regulatory inspections • Experience of Line Management including managing a team and developing staff	Application Form, Interview & References
Skills/Knowledge	
Essential • Detailed knowledge of UK Clinical trial regulations, GCP and regulatory framework	Application Form, Interview & References

• Knowledge of the requirements of clinical trials and clinical research projects during their life-cycle especially at the start-up stage • Knowledge of systems and processes required to conduct clinical trials in accordance with clinical trials regulations • Knowledge of clinical trial design issues in conducting oncology studies • A detailed understanding of the clinical trials approval process to conduct clinical research in the UK • 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 • Knowledge of developing budgets for clinical trials including AcORD process • Excellent report writing skills • Knowledge of Visio and or MS Project	
Other Requirements	
Essential • 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 **Desirable** • 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 & References
Physical	
Circumstances • Able to work on both sites and to be flexible to meet the needs of the role • Right to work in the UK.	Interview, Application Form, References & Occupational Health Review

The above attributes have been identified by management to be necessary for this post, and will be used when short listing applicants for interview.

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.

Safeguarding & Wellbeing of Children and Vulnerable Adults
The Trust is committed to safeguarding and promoting the welfare of children and vulnerable adults. To achieve our commitment, we will ensure continuous development and improvement of robust safeguarding processes and procedures that promote a culture of safeguarding amongst our workforce. All staff are expected to be aware of national, organisational and departmental policies and procedures on safeguarding and promotion of the wellbeing of children and vulnerable adults and should be able to communicate this to others.

Health and Safety
All staff is 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.

Customer Service Excellence
All staff is 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.

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.

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.

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.

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 organisation, in which case it will be reviewed in conjunction with the post holder.

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.