Greater Manchester Mental Health
NHS Foundation Trust

Job Description

Post Title	Clinical Trials Manager
Band	7
Directorate	Research & Innovation
Location/Base	Rawnsley Building
Responsible to	Head of Research & Innovation Office
Accountable to	Associate Director of Research & Innovation

Job Summary/Purpose

The postholder will be a senior member of the Research and Innovation team and will be responsible for the operational management of the commercial delivery team and dementia research team. The postholder will ensure there are systems in place for accurate and timely research project notification and approval and that such projects meet all the necessary research governance and regulatory requirements required for the Trust to either sponsor or host them. They will also ensure that their Clinical Research Network-funded staff are utilised effectively and work collaboratively with the relevant network managers. They will liaise with Chief Investigators regarding recruitment to individual portfolio studies and with finance colleagues to ensure that projects are accurately costed. They will be responsible for ensuring appropriate monitoring is in place for CTIMPs and liaise with pharmacy to ensure compliance with Good Clinical Practice. The post holder will have a key role in supporting and providing advice to researchers.

Main Duties & Responsibilities

Heading	Duty/Responsibility
Research Initiation and Setup	To lead on developing commercial activity within the Trust, including feasibility studies. To respond to feasibility requests for CTIMPs promptly. Work with local research leads to promote and encourage new and ongoing research studies, attending and presenting at local meetings as required. To work in conjunction with the Clinical Research Network staff to ensure that research projects are processed in a timely manner to meet funding deadlines and that the NIHR CRN portfolio is appropriately managed. Working closely with the research office, take a lead on ensuring researchers are properly advised regarding CTIMP administrative research procedures. This will include project registration, data extraction, ethical issues, financial arrangements, indemnity, intellectual property and funding opportunities. To liaise with and assist the study team regarding protocol development, Research Ethics, HRA, MHRA and other regulatory submissions and funding arrangements as required.

	To be responsible for the efficient administrative set-up of all the studies within the commercial Mental Health and Dementia specialities. To act as a pivotal point of contact with pharmaceutical companies, study Sponsors, Clinical Trials Units, Clinical Research Organisations, Research Office and Research Networks. To liaise with the Clinical Research Delivery Manager -Pharmacy clinical trials team, Laboratories and radiology, and R&I finance team regarding feasibility and resource requirements of studies after discussion with the lead investigator. To liaise with the Trust Research Office to gain Trust R&D approval. To ensure the study team has the capacity to conduct proposed studies within its current workload and activity.
Clinical Trials	To work with Trust Pharmacy in costing and support of Clinical Trials of Medicinal Products. To establish and ensure arrangements to provide compliance with pharmacovigilance requirements, including: Ensure SAEs and SUSARs for Commercial Trials and CTIMPs are appropriately managed and reported required parties. To ensure that clinical trials have the necessary approvals and permissions (eg ethics opinion, Clinical Trial Authorisation) and contractual arrangements (eg with participating sites, sponsor, pharmacy) in place before Research approval is granted. This will include negotiation of financial and contractual issues relating to commercial and academic clinical trials (and other research undertaken in the Trust) and liaison with the Pharmacy Clinical Trials team.
Leadership/Management	To provide professional leadership for the clinical trials team. To proactively ensure the provision of a comprehensive, high quality and efficient administrative service, including identifying improvements to team and/or department working practices, implementing policies and affecting change by proposing amendments/improvements. To manage research programmes ensuring that priorities are identified and dealt with and that problems are resolved as quickly as possible, working within Trust and R&I priorities and deadlines. To liaise with external bodies, such as the LCRN, Sponsors, NHS

	RECs, and others, in delivery of duties as necessary. To co-ordinate the work of the clinical trials team (including nursing staff - dependent on the organisational structure of the team), ensuring that adequate arrangements are in place to cover the work of absent staff and undertaking those duties if necessary.
Analytical and Judgmental Skills	To use audit, quality improvement and research methods to understand issues in the delivery of research in own area, and to find potential solutions relevant to the service. To ensure maintainance, in conjunction with other members of the R&I department, of a robust file management system for paper-based and electronic files for matters concerning the administration of research projects in commercial and dementia research.
Research Delivery	To lead on monitoring of Trust recruitment targets, including first participant into studies (FPI). Assess and evaluate the progress of on-going clinical trials and research by implementing systems and processes to ensure that that local and national R&D targets (including recruitment to time and target and meeting R&D approval time targets) are met. To work collaboratively with the GM Clinical Research Network and the Clinical Research Delivery Manager to ensure that Research Delivery staff work effectively to ensure recruitment to time and target for portfolio research studies. Facilitate recruitment to clinical research to ensure recruitment targets are achieved. Recognise actual/potential barriers to research and implement strategies for resolution. To support the Head of R&I and senior team on strategies for efficient use of network-funded delivery-focused staff in achieving Trust and CRN objectives and recruitment targets. To develop a strategy for liaison and communication with Chief Investigators of commercial and dementia portfolio studies regarding recruitment targets and performance. To develop department and/or trial specific Standard Operating Procedures (SOPs) and Work Instructions where appropriate, ensuring they are revised and distributed as specified to the relevant teams. Contribute toward the R&I Communications approach regarding Research Performance, Commercial Trial activity, Dementia Research Centre activity and CTIMPs.

	To assist senior staff within R&I with project management and service development, including grant, business cases and other funding applications to support the work of the Trust. To ensure R&I KPIs (Key Performance Indicators); including but not limited to - time to recruit first patient, patient recruitment to time and target - are recorded in a timely and accurate manner as per Trust requirements/policy. To inform Principal Investigators (and R&I via the CTM/R&IM) where there are problems or delays in recruiting patients, achieving targets or issues within the clinical trials team that will impact on the delivery of active or proposed studies for the Trust. To work with colleagues in R&I to provide information for Trust-wide electronic information systems to track patient accrual, recruitment targets and speciality activity. To provide reports on R&I activity. Oversee compliance with RPEAK, including the timely upload of Recruitment Activity for the Trust.
Study conduct	Oversee the research team in creation of study schedules to ensure scheduled patient follow-up visits and assessments take place in accordance with the study protocol. To ensure tissue and biomaterial collection and storage is implemented according to SOPs, and liaise with the Trust's HTA licence manager regarding collection, storage and transfer of tissue samples when there are compliance queries. To keep abreast of Trust-wide research SOPs and policies and ensure the research team are aware and conducting research according to these SOPs and policies. Ensure the team maintain Study Site/Master Files which are inspection-ready at all times. Ensure appropriate administrative processes are in place for completion of Adverse Event and Incident forms, reporting and follow up to resolution, as the study protocol and regulations require. To provide progress and other reports, as required, to all relevant parties, prepare presentations on behalf of the study team and take part in study/team meetings. To communicate with the Trust Research Office, Sponsors, funders, pharmaceutical companies, internal and external study personnel and outside agencies in a professional manner, maintaining an

	efficient flow of information to sustain smooth running of clinical trials. To ensure all study documents are archived according to Sponsor and Trust requirements and SOPs/policies, and a formal retrieval system is in place within research team.
Responsibilities for Financial and Physical Resources	Maximise opportunities for external income within commercial, dementia and addictions research. Take the lead on supporting the R&I Finance Manager with raising clinical trial invoices (as required). Assist with the identification and dissemination of research funding and training opportunities in own areas. To undertake contract financial negotiations with trial Sponsors/Clinical Research Organisations. To ensure financial arrangements are in place for studies with the R&I finance team, including cost recovery, invoicing and travel expenses. To ensure study costs are paid and tracked efficiently. To identify any resource issues in administrative workload within the team. With the assistance of the Research Nurse Lead, prioritise and delegate the administrative workload across the department and ensure efficient management and delivery of research study activity. Utilise excellent written and verbal communication to promote partnerships between pharmaceutical, biotech, medical device and diagnostic companies and the Trust, in order to drive increased investment. Develop and manage key R&I collaborations, which can often be highly confidential and highly sensitive. Facilitate collaborations between funders of research, including industry and charities, prioritising those of greatest significance to the Trust.
Trust Mandatory On-going Requirements - to be met by the candidate after	• To undertake any other reasonable duty, when requested to do so by an appropriate Trust manager. • To understand and comply with all Trust policies, procedures, protocols and guidelines.

commencing in post, these will not be assessed at the recruitment stage	• To understand the Trusts Strategic Goals and how you can support them. • To understand the need to safeguarding children and vulnerable adults and adhere to all principles in effective safeguarding. • To carry out all duties and responsibilities of the post in accordance with Equal Opportunities, Equality and Diversity and dignity in care/work policies and principles • To avoid unlawful discriminatory behaviour and actions when dealing with the colleagues, services users, members of the public and all stakeholders. • To access only information, where paper, electronic, or, in another media, which is authorised to you as part of the duties of your role. • Not to communicate to anyone or inside or outside the NHS, information relating to patients, services users, staff, contractors or any information of a commercially sensitive nature, unless done in the normal course of carrying out the duties of the post and with appropriate permission. • To maintain high standards of quality in corporate and clinical record keeping ensuring information is always recorded accurately, appropriately and kept up to date. • To ensure their day to day activities embrace sustainability and reduce the impact upon the environment by minimising waste and maximising recycling; saving energy; minimising water usage and reporting electrical faults, water leakages or other environmental concerns to the facilities department or their line manager. • Take reasonable care of the health and safety of yourself and other persons • To contribute to the control of risk and to report any incident, accident or near miss • To protect service users, visitors and employees against the risk of acquiring health care associated infections. • To take responsibility for your own learning and development by recognising and taking advantage of all opportunities to learn in line with appraisal and supervision.

Further Information for Postholder(s)

This job description is not exhaustive, but is intended to give an overall picture of the role. Other duties within the general scope of the post may be required from time to time. The duties of the post and job description can be reviewed through the agreed process. All information obtained or held during the post-holders period of employment that relates to the business of the Trust and its service users and employees will remain the property of the Trust. Information may be subject to disclosure under legislation at the Trust's discretion and in line with national rules on exemption.

All Trust sites have been designated a no smoking area. The post holder is therefore advised smoking is not permitted within the hospital premises or grounds or whilst representing the Trust in the course of their duty. While the Trust will not discriminate against employing smokers, all prospective employees should be aware of this policy

Person Specification

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Essential Criteria - The qualities without which a post holder could not be appointed.	**Desirable Criteria -** Extra qualities which can be used to choose between candidates who meet all the essential criteria	**How Assessed –** **AP =** Application form **IN** = Interview **OA** = Other Assessment
Education / Qualifications - to be able to complete the duties as laid out on the Job Description		
Educated to Masters degree level or equivalent experience.	Postgraduate doctoral degree or equivalent experience	AP
Experience - to be able to complete the duties as laid out on the Job Description		
Experience of working in a senior administrative/managerial role in a NHS R&D environment Experience of managing research to defined metrics Experience of negotiating research contracts with funders and commercial organisations. Experience of working with networks and external organisations, e.g. universities.	Experience of working with industry, Universities and other partners Research experience in a clinical environment Experience in HR and Management Related Issues Experience of delivering	AP IN

Project management experience and familiarity in dealing with complex situations requiring analysis and interpretation Experience of developing policies and procedures and their translation into practice Experience of developing and maintaining comprehensive and systematic systems for collecting and processing information Staff management experience	training and/or working in an advisory capacity Experience of working in the industry research sector		
Knowledge - to be able to complete the duties as laid out on the Job Description			Rese in a envi
The post holder should: In depth knowledge of NHS R&D strategy and NHS research agenda. Comprehensive knowledge and understanding of standards and legislation that govern research practice in the NHS Knowledge of regulatory issues surrounding the conduct of clinical research especially all phases of CTIMPs In depth knowledge of the requirements of NHS Research Management Systems Knowledge of databases and their implementation and management	University R&D systems and policies. Experience of trial monitoring processes	AP IN	
Skills and Abilities - to be able to complete the duties as laid out on the Job Description			Expe deliv and/ advis
Comprehensive IT skills including MS Word, Excel, Access (and other database packages), PowerPoint, Publisher, Internet and email. Excellent organisation, administration, and project management skills Excellent communication and interpersonal skills including the ability to negotiate and		AP IN	

persuade others. Enthusiastic, resolute and flexible approach to work Experience of liaising with different professions and organisations and/or working in a multidisciplinary environment. Ability to influence, negotiate with and motivate senior clinical professionals to achieve results Excellent organisational skills Experience of working to tight deadlines and ability to manage a range of priorities. Able to work independently and flexibly and use own initiative Effective time management skills		
Other Requirements - to be able to complete the duties as laid out on the Job Description		
There is a frequent requirement to travel across the footprint of the Trust to attend meetings and events relevant to the role, mainly at Trust bases or Clinical Research Network locations, but occasionally at other locations.		AP IN

The Trust will consider any reasonable adjustments to the recruitment and selection process and to employment for applicants who have protected characteristics under the Equality Act 2010.

Drawn up by: Sophie Faulkner & Natalie Garrett
Designation: Clinical Research Delivery Manager & Head of R&I
Date: 09.04.2024