

Job Description

Job Title:	Senior Trial Manager
Band:	Band 7
Base:	You may be required to work in other designated locations of the Trust as well as your primary base. In particular, flexibility is required across the three main hospital sites (Leicester Royal Infirmary, Leicester General Hospital and Glenfield Hospital). If your initial location is one of these sites excess travel reimbursement would not apply for a permanent or temporary change of base.
Reports to:	Lead Trial & Quality Manager
Accountable to:	Assistant Director of LDC Research Operations

Find out more about working with us:

<https://www.leicestershospitals.nhs.uk/aboutus/work-for-us/>

Job Summary	<p>The Senior Trial Manager is self-motivated, accessible and responsive, supporting the Lead Trial and Quality Manager and wider Leicester Diabetes Centre (LDC) team with trial management responsibility for research delivery, within the speciality of diabetes and other long term conditions (LTC).</p> <p>The post holder will have high level communication skills enabling maintenance of high quality education and research within a complex and challenging environment with often conflicting priorities.</p> <p>The post holder will act as a trial management expert and professional resource for the multidisciplinary team, external collaborators, students, patients and carers; and will be responsible for the oversight and management of non-commercial clinical trials being undertaken within the LDC.</p> <p>The post will ensure all trial activity is conducted in accordance with ICH GCP and Research Governance guidelines and will support the Lead Trial and Quality Manager and LDC Executive in providing strategic and operational direction for the LDC's diabetes research agenda.</p>
Service Delivery	<ul style="list-style-type: none"> • Support the Lead Trial and Quality Manager to lead, project manage and report the set-up and delivery of all clinical trials across the LDC including complex multi-site CTIMP trials. • Ensure trials are delivered to time and target through the effective management and supervision of staff. • In conjunction with the Lead Trial and Quality Manager be responsible for the trial management costings of studies and overall management of trial finance. • Provide operational strategic support to the LDC Directors and Executive Team.
Staff	<ul style="list-style-type: none"> • Responsibility for day to day management of the LDC's trial management team, including recruitment, retention, training, appraisals and the management of performance in line with corporate and local guidelines and policy.

	<ul style="list-style-type: none"> • The post holder will support the development, maintenance and review of financial procedures and policies relating to trial activities. • Ensure sufficient resources are available to meet the needs of the service and that studies are resourced to meet the needs of the study protocol, regulatory requirements and good practice guidelines. • Support the Lead Trial and Quality Manager in providing specialist trial management training to the research team and actively promote lifelong learning and personal development. • Provide supervision to trainee's and apprentices as required. • Act as a role model to junior staff, through effective leadership. • Act as the LDC's source of trial management knowledge and expertise. • Maintain own professional development. • Deputise for the Lead Trial and Quality Manager, Operations Director and other members of the Senior team at meetings, conferences, seminars as appropriate.
<p>Policy & Service Development</p>	<ul style="list-style-type: none"> • The post holder will support the LDC to strategically and operationally facilitate service development and provide advice on all issues related to trial management including reporting, trial authorisation, research governance and contributing and supporting to LDC wide policy development.
<p>Communications</p>	<ul style="list-style-type: none"> • Establish, develop and maintain effective working relationships between relevant stakeholders, practitioners, academics, clinicians and managers within the research speciality, locally, nationally and internationally. • Communicate and liaise with patient and user groups to incorporate patient user involvement in all areas of

	<p>research.</p> <ul style="list-style-type: none"> • Promote and facilitate participant recruitment through effective communication with CCG governance teams and Clinical Research Networks. • Develop a working partnership between the Trust, academic and support staff at local and external NHS and Universities. • Actively participate in local, national and international travel and networking to maintain and develop an expert level of knowledge in the speciality. To increase research capacity and generate new income.
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KEY WORKING RELATIONSHIPS

- Clinical Directors of LDC
- Assistant Director of LDC Research Operations
- Lead Trial and Quality Manager
- Patient Recruitment Centre (PRC) Business Manager
- Chief Investigators/Principal Investigators
- Lead Research Nurse
- Internal and external Senior and junior academics and researchers
- Staff at all levels, both clinical and non-clinical
- Members of the Joint UHL/UoL Research and Innovation Office
- Governance managers of other NHS and HEI organisations
- Auditors and regulators
- Other Corporate departments including Human Resources of the Trust and UoL
- Contracts and IP managers in UHL and UoL and other NHS/HEI organisations

- Clinical research Network East Midlands
- Primary care

KEY RESULT AREAS

- Support the Lead Trial and Quality Manager, Operations Director and LDC Executive in developing and delivering LDC strategies and overseeing the operational management of the LDC's Trial Management function and portfolio.
- Work across all areas of the LDC's clinical delivery teams to ensure a seamless approach to trial management e.g. work in collaboration with the PRC, BRC and ARC teams.
- Set-up, lead, project manage own portfolio of complex multi-site interventional trials
- Oversee the set-up, delivery and close-out of all the LDC's clinical research trials, including staff management, supervision and allocation, contract and IP negotiation, financial management and reporting of trial income and progress.
- Ensure the development and delivery of trials and associated projects are set-up and delivered to time and target; including putting into place remedial plans and monitoring outcomes.
- Act as a lead for the speciality of trial management and other relevant research governance areas as applicable. Putting into place policies and procedures to ensure the effective running and conduct of clinical trials across the LDC.
- Put into place procedures to ensure all projects are undertaken in accordance with ICH GCP and Research Governance guidelines, and ensure trials are 'audit ready'.
- Be responsible for conducting and/or overseeing Research Ethics Committee submissions/authorisations and NIHR adoption for new projects as required and manage/supervise others as appropriate.
- To undertake research and service development aligned with LDC priorities and strategic direction.
- To provide supervision, line management and professional development for the trial team including supervision of higher degree students and trainees as appropriate.

- Support the submissions of grants and bids for future research funding as required
- Lead and/or support the submission and publication of original research papers as required.
- Demonstrate expertise in the field of trial management, and the provision of support and advice as required. This includes the delivery of training sessions to research staff and healthcare professionals of all levels.
- Disseminate knowledge and skills to mentor junior staff.
- Be responsible for the preparation of senior level summary reports, presentations and papers locally, nationally and internationally.
- Provide expertise in the relevant area of clinical or professional practice in diabetes and other LTC's.

GENERAL

This job description indicates the main functions and responsibilities of the post. It is not intended to be a complete list. You may be required to undertake other duties from time to time as we may reasonably require.

You will be required to maintain compliance with all statutory and mandatory training requirements.

The link to the Trust's policies and procedures is:

<https://secure.library.leicestershospitals.nhs.uk/PAGL/SitePages/Home.aspx>