1 Advertisement

Post Title: CTU Senior Trial/Quality Assurance Manager
School/department: Brighton and Sussex Medical School/ Clinical Trials Unit
Hours: part-time hours considered up to 0.6 FTE. Requests for flexible working, including working from home options will be considered (subject to business need).
Location: Brighton, United Kingdom
Contract: Permanent
Reference: 20879
Salary: starting at £44,414 to £52,841 per annum, pro rata if part-time.
Placed on: 30 June 2023
Closing date: 21 July 2023. Applications must be received by midnight of the closing date.
Expected Interview date: To be confirmed.
Expected start date: To be confirmed.

An exciting opportunity has arisen for a new post within the Brighton and Sussex Clinical Trials Unit. We are seeking to appoint a senior trial and quality assurance manager. The post holder will be responsible for the line management of the CTU Trial Managers. The post holder will also be responsible for taking a leading role in the implementation and management of quality assurance systems for the Brighton and Sussex Clinical Trials Unit

The ideal candidate is educated to degree level or with equivalent experience, especially in Quality Assurance, with a proactive, positive and flexible attitude, and exceptional communication skills. You will have experience of working in NHS or Academic research and have up-to-date knowledge of all regulations and guidelines applicable to clinical trials. There may be a requirement to travel within the UK to research sites.

The Brighton and Sussex Clinical Trials Unit is based in the Brighton and Sussex Medical School at the University of Sussex. The CTU gained full registration in March 2023. BSCTU is involved in the design, conduct and analysis of RCTs and CTIMPs encompassing a range of disease areas (www.bsms.ac.uk/ctu). Through the new Brighton and Sussex Health Research Partnership the CTU works increasingly closely with R&D departments at partner NHS Trusts, especially University Hospitals Sussex NHS Foundation Trust and Sussex Partnership Foundation Trust.

For further information please contact: Wendy Wood, BSCTU Director w.wood@bsms.ac.uk

The University is committed to equality and valuing diversity, and applications are particularly welcomed from women and black and minority ethnic candidates, who are under-represented in academic posts in Science, Technology, Engineering, Medicine and Mathematics (STEMM) at Sussex.

For full details and how to apply see: www.brighton.ac.uk/jobs www.bsms.ac.uk

The University of Sussex values the diversity of its staff and students and we welcome applicants from all backgrounds.

2. Job Description

Job Title:	CTU Senior Trial /Quality Assurance Manager
Grade:	Grade 8
School/Division:	BSMS / Clinical Trials Unit
Location:	Watson Building, UoB
Responsible to:	CTU Director
Direct reports:	CTU Trial Managers,
Key contacts:	CTU Statisticians, Joint Clinical Research Office, Trial managers and other staff within R&D departments at NHS partners, Research & Enterprise offices at the Universities of Sussex and Brighton, the Health Research Partnership (HRP), BSMS Finance, BSMS Researchers
Role description:	The post holder will be responsible for the line management of the CTU Trial Managers and oversight of the CTU trial portfolio. The post holder will also be responsible for taking a leading role in the implementation and management of quality assurance systems for the Brighton and Sussex Clinical Trials Unit. The post holder will also provide support to researchers during the grant application process, where CTU collaboration is required and will provide study set up support for all CTU studies. They will also act as point of contact for researchers and Sponsors to provide advice on trial and quality assurance management issues, across BSMS.

PRINCIPAL ACCOUNTABILITIES

1. Lead, manage, promote and maintain a high quality Clinical Trials Unit, engendering a culture of continuous improvement.

2. Ensure the delivery of outputs of the department.

3. Ensure compliance with all relevant legislation and University policies, interpreting the same and advising on their practical application.

4. Work in partnership with colleagues across the Health Research Partnership to ensure seamless support for CTU related activity is available across partner organisations

5 Provide ongoing professional leadership and management in the design and implementation of legal and regulatory framework in relation to clinical trials to ensure that they are robust, auditable and concur with accepted best practice.

6 Represent the CTU at National meetings and deputise for the Director as required.

7 Play an active role in the development of the infrastructure to support clinical research and governance within BSMS/US.

8 Work with key stakeholders to develop an initial audit plan, including scope, resource plans and costs based on the outcomes from an initial review of CTU SOPs and Risk Assessments. Get the project plan through initial approval from CTU Senior Management.

9 Provide the day-to-day leadership and management of QA for BSCTU, through all aspects of the project life cycle, co-ordinating the CTU team in a matrix environment and liaising closely with the study sponsors.

KEY RESPONSIBILITIES

1. Departmental Management and Leadership

1.1 Provide management and leadership to motivate the department to achieve targets and objectives

1.2 Ensure the availability of resources to achieve targets and objectives including the selection, induction, performance management and development of all members of the department

1.3 Ensure departmental understanding and application of operational standards are embedded in the departmental culture and methods of working

1.4 Support the development of others, providing training and coaching in area of expertise, including annual appraisals.

1.5 Foster an ethos of continuous improvement both within the CTU and wider research environment.

2. Service Delivery

2.1 Working within overall university policy and procedure, ensure the effective management of responsibilities in the area of expertise (Trial Management and Quality Assurance). Plan and allocate resources to support the achievement of departmental targets and objectives.

2.2 Ensure effective systems and procedures are in place to support the achievement of key performance targets in area of responsibility.

2.3 Contribute to the development of departmental/functional strategic planning process

2.4 Ensure the delivery of improvements to systems and procedures to maintain effective service delivery within area of responsibility.

2.5 Ensure appropriate records and documentation are maintained commensurate with policy and procedure.

2.6 Provide reports and other communication media internally and externally as appropriate. To undertake analysis, interpretation and presentation of complex information to inform decisions related to subject area

2.7 Identify critical issues when resolving problems particularly where there is complex or competing information and use university policy and objectives to make decisions.

3. Policy and Procedure

3.1 Based on a broad and deep set of knowledge and experience, interpret policy and procedure, providing advice on the application of policy as required.

3.2 Contribute to the shaping of policy decisions and improvement in area of expertise.

3.3 Ensure appropriate governance is in place for area of expertise.

4. Customers and Stakeholders

4.1 Proactively work with internal and external stakeholders, colleagues or students to ensure the effective service delivery, initiate and develop relationships, providing data and information to inform decisions as necessary, showing appropriate sensitivity when needed.

4.2 Persuade, influence and negotiate as appropriate to further the objectives of the CTU and University.

5. Key CTU Responsibilities

5.1 Responsible for oversight and management of the Clinical Trial Managers who are working on CTU led studies, this may include TMs working across different sites.

5.2 Work with researchers and other departments in the development of grant applications where CTU collaboration is required, along with the CTU Director.

5.3 Work with Chief Investigators to ensure the timely set up of CTU studies once grant funding has been awarded.

5.4 Review existing quality assurance (QA) systems, processes and SOPs within the BSCTU regarding their compliance with applicable regulatory and good clinical practice requirements, as expected by sponsors and regulatory bodies.

5.5 Develop and implement processes within the BSCTU to monitor compliance with SOPs and regulatory requirements and ensure standardisation of working practice across the Unit.

5.6 Provide reports for the study team and senior leadership team with feedback and any proposed remedial actions and check these are actioned and completed.

5.7 Lead on developing and maintaining risk assessments for each BSCTU-managed study, proposing appropriate mitigations as required and undertake periodic reviews of existing studies to determine the risk level, ensuring appropriate levels of risk management, risk mitigation and monitoring are in place.

5.8 Produce reports regarding any shortcomings in existing systems to the senior leadership team and propose appropriate remedial actions.

5.9 Develop and maintain business and project plans for the implementation and running of QA work.

To carry out any other duties that are within the employee's skills and abilities whenever reasonably instructed.

This Job Description sets out current duties of the post that may vary from time to time without changing the general character of the post or level of responsibility entailed.

INDICATIVE PERFORMANCE CRITERIA

- Leading a team of 5-10 staff
- With the CTU Director, assist in the management of the CTU budget to ensure continuity of grant income

- With the CTU Director, assist to ensure the continued registration of the CTU within the UK Clinical Research Collaboration CTU Network.

- The post holder reports to the CTU Director working under broad direction to enable the post holder to manage their own work and that of their team members, to achieve their agreed objectives. The role holder will play a key role as part of the Divisional leadership team in supporting the achievement of the strategic and operational goals of the University, Professional Services & their Division. The post holder is expected to work collaboratively across the University and with key stakeholders to deliver single team working that efficiently and effectively supports the achievement of those goals and objectives.

- Support achievement of the Division's/Unit's/School's compliance with all applicable statutory and regulatory compliance obligations, including (but not limited to): UKVI, Health & Safety, the Prevent Duty, data protection, Competition and Markets Authority requirements and equal opportunities, as appropriate to the grade and role. Additionally, to promote good practice in relation to University policy, procedure and guidance in relation to those compliance matters in respect of students, staff and other relevant parties.

- Balance effectiveness and cost-efficiency in the management of the budgets you are accountable for, demonstrating compliance with Value for Money and Return on Investment principles to support the University's strategic aim to achieve a world-class standard of teaching and research by managing our resources effectively and efficiently

PERSON SPECIFICATION

ESSENTIAL CRITERIA

1. Educated to degree level, or other equivalent experience or qualification, or relevant level of experience, working at a senior level in clinical research or clinical trial management

2. A detailed applied and theoretical knowledge and understanding of Clinical Research

3. Effective management skills

4. Well-developed oral and written communication skills with the ability to present policy and procedure in a way that can be understood the audience.

5. Planning and organisational skills, including project management, with the ability to delegate to team members where appropriate.

6. Well-developed interpersonal skills with the ability to effectively influence, persuade and negotiate in area of expertise, effectively contribute to team working to build and develop working relationships.

7. Analytical skills with the ability to generate effective solutions and make effective decisions

8. Commitment to customer excellence

9. Effective IT Skills on MS platform.

10. [details of essential criteria].

ESSENTIAL ROLE-SPECIFIC CRITERIA

- Maintain an excellent knowledge of emerging policies and changing legislation from government departments and external bodies which may impact the service.
- Experience of working in a Quality Assurance role in clinical research.
- Experience of project development, data collection, auditing, monitoring, and dissemination of results.
- Thorough understanding of ethical review process and scientific review
- Specialist expert knowledge of Research Governance and Quality Assurance
- Specialist expert Knowledge of Research Management Information Systems
- Expert Knowledge of clinical trials management, guidance and regulations
- Experience of project and change management.

DESIRABLE CRITERIA

- Knowledge of the Higher Education sector
- Knowledge and understanding of NHS structure and organisation
- Budget management and study costings