UNIVERSITY OF SUSSEX

1 Advertisement

Post Title: Clinical Trial Manager
School/department: Brighton and Sussex Medical School, Brighton and Sussex Clinical Trials Unit (BSCTU)
Hours: Part-time hours considered up to 18.75 hours per week Requests for flexible working, including working from home options will be considered (subject to business need).
Location: Brighton, United Kingdom
Contract: fixed term until 30 June 2024
Ref: 10257
Salary: starting at £35,333 to £42,155 per annum, pro rata
Placed on: 14 November 2022
Closing date: 08 December 2022. Applications must be received by midnight of the closing date.
Expected Interview date: 20 and 21 December 2022
Expected start date: ASAP

An opportunity has arisen for a clinical trial manager within the Brighton and Sussex Clinical Trials Unit. We are seeking to appoint a trial manager to cover the study: **Increasing access to CBT for psychosis patients: a randomized controlled trial evaluating brief, targeted CBT for distressing voices delivered by Assistant Psychologists (GIVE 3).**

The ideal candidate is educated to degree level or with equivalent experience, proactive with a 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. Appropriate study training will be provided.

The Brighton and Sussex Clinical Trials Unit is based in the Brighton and Sussex Medical School at the University of Sussex with close working relations with Brighton and Sussex University Hospitals R&D department. The CTU gained provisional registration in May 2018. BSCTU is involved in the design, conduct and analysis of RCTs and CTIMPs encompassing a range of disease areas (www.bsms.ac.uk/ctu)

For further information please contact: Nicky Perry, BSCTU Director on n.perry@bsms.ac.uk or Prof Mark Hayward m.hayward@spft.nhs.uk

For full details and how to apply see our vacancies page

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. The School / Division

Please find further information regarding the school/division at Brighton and Sussex Medical School - BSMS

3. Job Description

The primary role of the post holder is to set up and support high quality clinical trials at the Brighton and Sussex Clinical Trials Unit (CTU). The post holder will be responsible to the CTU Director and the Chief Investigator of the studies.

The primary objectives of this post are:

- To establish and maintain effective management systems for the trial;
- To act as the Central Trials Unit contact for the trial;
- To liaise with all collaborating organisations and individuals as required ensuring the smooth running of the trial;
- To uphold the quality of the trial and compliance with the protocol, GCP and applicable standards and regulations.

Key Accountabilities/Primary Responsibilities:

Main areas of responsibility include:

- Overall efficient, day-to-day management of one or more trials/research projects.
- Establishment of procedures to ensure adherence to trial protocol, regulatory and administrative requirements, including pharmacovigilance;
- Writing, contributing to, or reviewing trial specific documentation (e.g. protocol, CRFs, trial plans and instructions) that is compliant with the Sponsors SOPS and
- BSCTU working practices and ensuring this is implemented and kept up to date.
- Responsible for the maintenance all trial files, including the trial master file, and oversight of site files
- Assisting in the securing of all necessary approvals for the trial and participating sites according to the UK Clinical Trials Regulations, ICH Good Clinical Practice, the European Directives on Clinical Trials and Good Clinical Practice, and the Department of Health's Research Governance Framework
- Ensuring sites have appropriate training, including conducting site initiation visits and maintaining necessary records
- Monitoring trial recruitment, providing support and motivation to recruiting staff as required. Identifying issues and feedback to Senior Trial Manager in a timely manner.
- Working with senior CTU staff and the Chief Investigator to ensure that the trial is conducted to a high standard to achieve targets and to predict and plan any changes

that warrant requests to changes in protocol, ethical and regulatory approvals, funding, or time

- Ensuring that good communication is maintained between the trial team, the CTU and recruiting site staff including the provision of regular and ad hoc information, both written and verbal, to trial participants and sponsors and stakeholders, to include reports, updates, guidance, newsletters and trial website

- Providing updates on the progress of the trial at regular Trial Management Group, Data Monitoring and Trial Steering Committees as required

- Preparing the trial specifications for the database with the statistician and database managers.

- Planning and supporting meetings and work of the various groups associated with the trial and ensuring appropriate minutes are taken of all trial related meetings

- Supervising data collection from sites and entering data within the CTU, e.g. SAE forms as required

- Supervising the data cleaning and validation, including querying and chasing missing data in a timely manner

- Contributing to writing and review of trial reports and publications

- Taking responsibility for the quality of the post-holder's own work

- Escalating potentially significant quality issues to the Senior Clinical Trials manager and Operational Manager

- Participating in training and development initiatives

- Willingness to travel.

- Cover for other studies/colleagues as required.

Person Specification

Criteria	**Essential**	**Desirable**

Qualifications, Knowledge and Experience:	Science Degree Understanding of clinical trial design and other types of clinical research studies Knowledge of UK Clinical Trials Regulations, ICH Good Clinical Practice, the European Directives on Clinical Trials and Good Clinical Practice and the Department of Health's Research Governance Framework Understanding of the requirements for effective data management in clinical research. Excellent IT skills including email, spread sheets, word processing, databases and the Internet, and working knowledge of MS Office.	Experience of setting up and managing clinical trials/other well designed research projects from protocol development to study close out. Experience of managing several projects that are often time pressured, concurrently. Evidence of ability to set up and maintain effective administrative systems in trials. Ability to evaluate risks inherent in clinical trials and decide those which should be prioritised to ensure that risks are properly managed. Knowledge of Data Protection Act
Planning and Organising:	Experience of working unsupervised and taking responsibility for setting and meeting targets, for own work and others. A methodical and accurate approach to work with attention to detail.	
Management and Teamwork:	Ability to supervise other members of the team, promote good working relationships and resolve difficult situations. Ability to work collaboratively and as part of a team.	Self-motivating. Willing to acquire new knowledge and skills. Willing to contribute to procedures and processes of the B&S CTU.
Communicating and Influencing:	Demonstrable communication skills in English language. Excellent communication (written and oral) and interpersonal skills.	Able to negotiate effectively

	Able to communicate complex information to a range of disciplines.	
Special Requirements:	Willing to travel within the UK/EU (may involve overnight stays).	

6. Terms and Conditions of the Post

For a summary of the terms and conditions of the post, see: http://www.sussex.ac.uk/aboutus/jobs/terms.