NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

Job Description

Nuffield Department of Primary Care Health Sciences

Job title	Trial Systems Manager
Division	Medical Sciences
Department	Nuffield Department of Primary Care Health Sciences
Location	Radcliffe Primary Care Building, Radcliffe Observatory Quarter, Woodstock Road, Oxford, OX2 6GG
Grade and salary	Grade 7 : £32,817 - £40,322 per annum
Hours	Full time
Contract type	Fixed-term (1 year)
Reporting to	Emma Ogburn, CTU Director of Operations
Vacancy reference	BZ20053
Additional information	*This vacancy is for internal applicants only*

The role

To provide key technical input to the development, testing and validation of CTU software such as electronic case report forms, databases and tracking systems that support our clinical trials. The successful candidate will be involved in testing, development and application support activities and ensure projects are released to specification. They will work closely with the trial delivery teams to understand requirements and develop specifications. They will be pivotal in the trial set up stage to ensure consistency between Trial Managers and other operational teams. Working closely with the department's communications team, the role will involve trial promotional work via website creation and management, coordination of social media activity and day-to-day trial communications. The role will include some programming tasks, so the successful candidate should have an interest in software development and a willingness to learn new programming methods and frameworks.

Responsibilities

This role will lead to the creation of the digital infrastructure for the CTU, from databases, to template libraries and mailing lists with the focus of the role on upskilling other colleagues in the department in order to teach techniques that can be automated. This would mean developing and leading teaching and/or drop in sessions to improve staff efficiency.

- Assist with the build, design and validation of template electronic case report forms (eCRF) and electronic patient reported outcome (ePRO) systems for clinical trials and other research studies
- Configure and support a trial management tracking system and provide suitable training for new and existing users
- Contribute to systems analysis, database development, programming, support, testing and validation
- Creation and writing of effective testing and validation procedures, working alongside other developers, to produce high quality applications
- Work closely with programmers, trial personnel, researchers and other end users to analyse and scope requirements, write specifications, and resolve technical issues
- Perform risk assessments, plan and perform validations for software and systems, including Performance Qualification (PQ), Operational Qualification (OQ) and Installation Qualification (IQ)
- Provide support and training to the trial delivery teams to ensure they can use the systems correctly
- Develop written procedures and other supporting documentation/podcasts and guidelines, adapting to evolving in-house or commercial applications
- Ensure appropriate filing and archiving of programming documentation, datasets and documented software

To undertake other duties as may be reasonably expected by line manager, this may include:

- Build, design and validate back end database systems, including but not limited to Access and other SQL servers
- Build, design and maintain a functioning CTU repository of essential documents from all sites
- Build, design and maintain a library of templates for the rapid creation of a trials in emergency situations or at short notice. This should also be used extensively to reduce repetitive work load at set up stage of Trials.
- Template library should include, eCRFs, Access databases, Word/Excel templates and any others programs that can be utilised to prevent duplication of effort.
- Lead staff training on the most frequently used software – Excel, Access, Outlook etc.
- Source new software that may be of use to the CTU and present a case for these to senior team on an ongoing basis.
- Set up new techniques to support trial set-up such as enabling document sharing with sites, automated GDPR-compliant mailing lists, coordinating social media account activity and other forms of communications to support patient recruitment and engagement.
- Help pioneer and train staff in new data presentation techniques. This ranges from using website and social media to support recruitment into trials (under the guidance of the department communications team) to using new graphical and infographic programmes to help staff better present and display our results and work, all in line with University and funder brand guidelines.
- Be proactive in suggesting ways to improve functioning of the CTU.
- Contribute to Department and CTU committees. Being a full and active member of the CTU trial managers working group.
- Develop and maintain excellent relationships with senior colleagues within the University and Department.
- Other tasks as appropriate to the role

Pre-employment screening

All offers of employment are made subject to standard pre-employment screening, as applicable to the post.

If you are offered the post, you will be asked to provide proof of your right-to-work, your identity, and we will contact the referees you have nominated. You will also be asked to complete a health declaration (so that you can tell us about any health conditions or disabilities so that we can discuss appropriate adjustments with you), and a declaration of any unspent criminal convictions.

We advise all applicants to read the candidate notes on the University's pre-employment screening procedures, found at: www.ox.ac.uk/about/jobs/preemploymentscreening/.

Selection criteria

Essential selection criteria

- Degree in a medical science or equivalent experience
- Experience of working in clinical trial management having had experience of all tasks within the lifecycle of a trial.
- Experience of data management and tracking within the lifecycle of a trial.
- Highly IT literate with an excellent proven range of IT skills (including MS Word, Excel, Access and Project)
- Demonstrated interest in software development and a willingness to learn new programming methods and frameworks
- Experience of website development and management or using existing content management systems.
- Experience of authoring and reviewing documents to varied audiences, including working guidelines.
- Experience of delivering training and presentations to varied audiences.
- Excellent communication skills, both written and verbal.
- Track record of being a proactive team player.

Desirable selection criteria

- Up to date knowledge of the regulatory and governance requirements for UK clinical trials.
- Experience of being involved with audits and inspections eg: by MHRA
- Ability to prioritise and manage own and others workloads in a calm and professional manner.

- Demonstrated ability to develop and maintain relationships with colleagues at various levels both within your organisation and externally
- Knowledge of GDPR and Information Governance requirements in handling sensitive personal data