ROLE PROFILE

Job Title: Clinical Trial Manager

School/Department: School of Medicine – Nottingham Clinical Trials Unit (NCTU)

Job Family and Level: Research & Teaching Level 4

Contract Status: Fixed-term for a period of one year

Hours of Work: Preferably full-time position (36.25 hours per week); however applications are welcome from candidates wishing to work part-time (minimum 29 hours per week). Please indicate on your application the hours you wish to work

Location: Nottingham Clinical Trials Unit, Queen’s Medical Centre, South Block

Reporting to: Senior Trial Manager

Purpose of the Role:
The role holder will be a key member of a multidisciplinary team undertaking high quality clinical trials within the Nottingham Clinical Trials Unit (NCTU), working closely with the Chief Investigators, other researchers and clinicians. They will be responsible for all trial management activities required to ensure efficient and successful completion of trials.

Working Environment:
Nottingham Clinical Trials Unit (NCTU) is a UK Clinical Research Collaboration registered Clinical Trials Unit (http://www.ukcrc-ctu.org.uk) based in the School of Medicine at the University of Nottingham. The unit’s mission is to conduct high quality, high impact multicentre trials to improve health and well-being. The unit has close links with local NHS Trusts (Nottingham University Hospital NHS Trust, Nottinghamshire Healthcare NHS Foundation Trust, and Derby Teaching Hospitals NHS Foundation Trust), the Institute of Mental Health and the School of Health Sciences.

NCTU has a broad portfolio of trials including studies evaluating medical devices, CTIMPs and complex interventions. Particular strengths and clinical areas with potential for further development are trials of skin conditions and wound healing, perinatal trials, gastroenterology, respiratory, stroke, mental health, hand surgery and genitourinary medicine. The unit currently has around 60 staff, and with the recent investment of strategic development funding from the University this is anticipated to expand to 100 staff over the next 3-5 years.

For further information see: www.nottingham.ac.uk/ctu

Main Responsibilities

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<th>Main Responsibilities</th>
<th>% time per year</th>
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<tr>
<td>1. <strong>Research</strong></td>
<td>25%</td>
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<tr>
<td>• Working with the Chief Investigator (CI) and the trial team to develop the research protocol</td>
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<td>• Contributing to developing trial documents for Research Ethics Committees and Regulatory Authorities approval (e.g. participant information sheet, and informed consent form) including co-ordinating input from the trial team. Similarly, managing any amendments and ensuring accurate version control</td>
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<td>• Contributing to the Trial Steering Committee and Data Monitoring Committee</td>
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<td>• Implement proven new strategies for trial management and participate in methodological research to improve trial efficiency.</td>
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• Work with the Chief Investigator and other members of the research team to ensure dissemination of the trial results, for example contributing to writing the trial report, preparing results for publication, and presenting at relevant conferences and other meetings

2. **Project Management**
   • Project management of the trial(s), working closely with Chief Investigator and NCTU trial team members to ensure project(s) milestones are met and the trial is delivered on time and within budget
   • Ensuring the trial is managed and conducted in compliance with the relevant SOPs and NCTU Quality Management System
   • Developing and maintaining risk assessment for the duration of the project, ensuring risks are identified and minimised, and escalated to the appropriate member of the research team when necessary
   • Monitoring recruitment against targets to identify problems and their potential solutions, and work with sites to implement corrective actions if required
   • Developing and maintaining excellent communication with the NCTU team, sites, co-investigators, Trial Management Group, trial oversight committees (Trial Steering Committee and Data Monitoring Committee), R&D offices, sponsors, funders and regulatory bodies
   • Ensuring accurate and timely trial records and reports are prepared to a high standard and submitted in a timely manner to regulatory and funding bodies, and others as required
   • Ensuring high quality organisation of trial meetings, including those for Investigators, Trial Steering Committees, Data Monitoring Committees, and Trial Management Groups
   • Design, undertake and deliver training to the research team both locally and nationally and, where appropriate, internationally

3. **Data Management**
   • Contributing to the multidisciplinary teams developing the Case Report Forms, and designing and testing the trial database(s)
   • Working with the NCTU data team and site staff to ensure timely and accurate data collection, monitoring data quality and completeness
   • Developing and implementing a trial monitoring plan to ensure high quality trial conduct, using a mixture of central monitoring and site visits, appropriate to the trial

4. **Line Management and Supervision**
   As appropriate, line management and/or supervision of trial management staff:
   
   **Line Management where appropriate to additionally include:**
   • Conduct annual and interim performance reviews
   • Deal with pastoral issues

   **Supervision to include:**
   • Allocating work and monitoring against deadlines
   • Identifying areas for staff development/training and providing such training where appropriate

5. **General Duties**
   • Keeping up to date with relevant clinical trial regulations and research governance
   • Any other duties appropriate to the grade and role of the post holder

This job description may be subject to revision following discussion with the person appointed and forms part of the contract of employment.

### Knowledge, Skills, Qualifications & Experience

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<th>Qualifications/Education</th>
<th>Essential</th>
<th>Desirable</th>
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<td><strong>Degree (or equivalent qualification) in a relevant subject OR</strong> Significant experience as a Clinical Trial Manager/Coordinator</td>
<td>PhD / MSc, preferably in a clinical trial related subject</td>
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<tr>
<td><strong>Skills/Training</strong></td>
<td>Excellent presentation and communication skills both written and oral</td>
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**Self-motivated and able to motivate and influence others within a multi-disciplinary team from a range of professional backgrounds and levels of seniority**

- Confident in prioritising and managing own workload and work with minimal supervision
- Ability to understand complex problems and challenges and apply knowledge to address them
- Excellent organisational skills with a flexible approach to working and the ability to multi-task
- Detailed understanding of statutory Clinical Trial regulations, GCP and research governance requirements
- Excellent computer skills, especially Microsoft Office software (Word, Excel, PowerPoint and Project)
- Excellent people management skills

**Experience**

- Experience of project management of clinical research with a track record of successfully completed trials
- Experience of preparing complex reports and trial related documentation
- Experience of working within a multi-disciplinary team, understanding the strengths and weaknesses of others to assist teamwork development
- Experience of line management / supervision of staff
- Experience in delivering training
- Experience of scientific writing
- Previous experience of work as a Clinical research Associate in an Industry setting
- Experience of MHRA and sponsor audits

**Other**

- Able and willing to travel nationally and internationally, for trial meetings or site visits as required
- Ability to work flexibly to meet the requirements of the role
- Willingness to adopt the Ethos and Principles of the School of Medicine to improve the student experience

**Background**

The post holder will work as part of a team and will have responsibilities for the initiation, delivery, management and coordination of all research activities for assigned projects in compliance with all relevant regulations and SOPs for trials.

**Working Environment**

The post-holder will be based at the Nottingham Clinical Trial Unit and will be part of a team reporting to the Senior Trial Manager. The Nottingham Clinical Trials Unit is housed within the Queen’s Medical Centre, C-floors, South Block. There is a highly collaborative work ethic which allows individuals to work closely with the various teams within the unit and gain from each other’s experience.

*The University of Nottingham strongly endorses Athena SWAN principles, with commitment from all levels of the organisation in furthering women’s careers. It is our mission to ensure equal opportunity, best working practices and fair policies for all.*