**University of Nottingham**

UK | CHINA | MALAYSIA

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| **Job title** | Clinical Trial Manager (fixed term) | **Job family and level** | Research & Teaching, Level 4 |
| **School/ Department** | School of Medicine, Nottingham Clinical Trials Unit (NCTU) | **Location** | Applied Health Research Building, University Park |

## Purpose of role

You 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. You will be responsible for all trial management activities required to ensure efficient and successful completion of trials.

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.

NCTU has a broad portfolio of trials including studies evaluating medical devices, medicines and complex interventions. The unit currently has around 80 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: http://www.nottingham.ac.uk/nctu/index.aspx

The School of Medicine recognises the importance of continuous professional development and therefore the importance of providing opportunities, structured support and encouragement to engage in professional development each year.

| | **Main responsibilities** (Primary accountabilities and responsibilities expected to fulfil the role) | **% time per year** |
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| 1 | **Research** <br> ▪ Working with the Chief Investigator (CI) and the trial team to develop the research protocol <br> ▪ 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 <br> ▪ Contributing to the Trial Steering Committee and Data Monitoring Committee <br> ▪ Implement proven new strategies for trial management and participate in methodological research to improve trial efficiency <br> ▪ Work with the Chief Investigator and other members of the research team to ensure dissemination of the trial results, for example | 15% |

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| | contributing to writing the trial report, preparing results for publication, and presenting at relevant conferences and other meetings | |
| 2 | **Project Management**<br>▪ Project management of the trial(s), working closely with Chief Investigator and trial team members to ensure project(s) milestones are met and the trial is delivered on time and within budget<br>▪ Ensuring the trial is managed and conducted in compliance with the relevant SOPs and Quality Management System<br>▪ 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<br>▪ Monitoring recruitment against targets to identify problems and their potential solutions, and work with sites to implement corrective actions if required<br>▪ Developing and maintaining excellent communication with the trial 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<br>▪ 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<br>▪ Ensuring high quality organisation of trial meetings, including those for Investigators, Trial Steering Committees, Data Monitoring Committees, and Trial Management Groups<br>▪ Design, undertake and deliver training to the research team both locally and nationally and, where appropriate, internationally | 35% |
| 3 | **Data Management**<br>▪ Contributing to the multidisciplinary teams developing the Case Report Forms, and designing and testing the trial database(s)<br>▪ Working with the data team and site staff to ensure timely and accurate data collection, monitoring data quality and completeness<br>▪ 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 | 35% |
| 4 | **Line Management, Supervision and General duties**<br>As appropriate, line management and or supervision of trial management staff:<br><br>Line Management where appropriate to additionally include:<br>▪ Conduct annual and interim performance reviews<br>▪ Deal with pastoral issues<br><br>Supervision to include:<br>▪ Allocating work and monitoring against deadlines<br>▪ Identifying areas for staff development/training and providing such training where appropriate<br><br>General duties to include:<br>▪ Keeping up to date with relevant clinical trial regulations and research governance<br>▪ Any other duties appropriate to the grade and role<br>▪ | 15% |

# Person specification

| | Essential | Desirable |
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| **Skills** | <ul><li>Excellent presentation and communication skills both written and oral</li><li>Self-motivated and able to motivate and influence others within a multi-disciplinary team from a range of professional backgrounds and levels of seniority</li><li>Confident in prioritising and managing own workload and work with minimal supervision</li><li>Ability to understand complex problems and challenges and apply knowledge to address them</li><li>Excellent organisational skills with a flexible approach to working and the ability to multi-task</li><li>Demonstrable understanding of statutory Clinical Trial regulations, Good Clinical Practice (GCP) and research governance requirements</li><li>Excellent computer skills, especially Microsoft Office software (Word, Excel, PowerPoint and Project)</li><li>Excellent people management skills</li></ul> | |
| **Knowledge and experience** | <ul><li>Experience of project management of clinical research with a track record of successfully completed trials</li><li>Experience of preparing complex reports and trial related documentation</li><li>Experience of working within a multi-disciplinary team, understanding the strengths and weaknesses of others to assist teamwork development.</li><li>Demonstrable understanding of statutory Clinical Trial regulations, GCP and research governance requirements</li></ul> | <ul><li>Experience of Primary Care trials</li><li>Experience of line management / supervision of staff</li><li>Experience in delivering training</li><li>Experience of scientific writing</li><li>Previous experience of work as a Clinical research Associate in an Industry setting</li><li>Experience of Medicine and Healthcare products Regulatory Agency (MHRA) and sponsor audit</li></ul> |
| **Qualifications, certification and** | <ul><li>Degree (or equivalent qualification) in a relevant subject **OR**</li></ul> | <ul><li>PhD / MSc, preferably in a clinical trial related subject</li></ul> |

| training (relevant to role) | ▪ Significant experience as a Clinical Trial Manager/Coordinator | |
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| **Other** | ▪ Able and willing to travel nationally and internationally, for trial meetings or site visits as required<br>▪ Ability to work flexibly to meet the requirements of the role<br>▪ Willingness to adopt the vision and values of the School of Medicine | |

# Expectations and behaviours

The University has developed a clear set of core expectations and behaviours that our people should be demonstrating in their work, and as ambassadors of the University's strategy, vision and values. The following are essential to the role:

**Valuing people**

Is always equitable and fair and works with integrity. Proactively looks for ways to develop the team and is comfortable providing clarity by explaining the rationale behind decisions.

**Taking ownership**

Is highly self-aware, looking for ways to improve, both taking on board and offering constructive feedback. Inspires others to take accountability for their own areas.

**Forward thinking**

Driven to question the status quo and explore new ideas, supporting the team to "lead the way" in terms of know-how and learning.

**Professional pride**

Sets the bar high with quality systems and control measures in place. Demands high standards of others identifying and addressing any gaps to enhance the overall performance.

**Always inclusive**

Ensures accessibility to the wider community, actively encouraging inclusion and seeking to involve others. Ensures others always consider the wider context when sharing information making full use of networks and connections.

# Key relationships with others

**Line manager**

Senior Clinical Trial Manager

**Role holder**

**Clinical Trial Manager**

**Key stakeholder relationships**

**Trial Team & CI** | Trial Coordinator & Trial Administrator (Direct Reports) | Colleagues