University of Nottingham
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Role profile

Job title	Trial Coordinator	Job family and level	Administrative, Professional and Managerial Level 3
School/ Department	School of Medicine, Nottingham Clinical Trials Unit (NCTU)	Location	Nottingham Clinical Trials Unit, University Park Campus

Purpose of role

To provide management and operational support for the Trial Manager in day-to-day running of the trial(s) to ensure effective and efficient trial conduct. You will work closely with the Clinical Trial Manager, Research Nurse, Research Practitioner, Chief Investigator, local Investigators, and the Senior Trial Manager to ensure successful completion of studies. You may work on more than one trial over time.

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

	Main responsibilities (Primary accountabilities and responsibilities expected to fulfil the role)	**% time per year**
1	**General Research-related Duties:** To provide management and operational support to the Trial Manager and wider team in effective and efficient trial conduct by: ▪ Supporting the CI and Trial Manager to write and prepare applications for submissions to the Health Research Authority (HRA), Research Ethics Committee (REC) and Regulatory Authorities (Medicines and Healthcare products Regulatory Agency – MHRA) ▪ Co-ordinating the implementation of all necessary trial approvals ▪ Assisting with development and writing of study related documents, reports and processes (e.g. protocol, participant information sheets, informed consent forms, case report forms etc.) in accordance with relevant Standard Operating Procedures (SOPs) ▪ Working with the Trial Manager to deliver trial-related training ▪ Working with the Trial Manager to monitor centre recruitment, data completeness and quality, and retention of participants in follow-up; and to identify problems, and implement strategies to overcome any identified problems ▪ Performing site monitoring according to the monitoring plan ▪ Preparing trial correspondence and communications e.g. newsletters, flyers, posters and other updates for centres	40%

	▪ Providing support to the Trial Manager by preparing documentation and contributing to Investigator, Trial Steering Committee, Data Monitoring Committee, and Trial Management Group meetings ▪ Working in accordance with Good Clinical Practice and undertaking regular training to keep up to date with all relevant research regulations and research methodology ▪ Contributing to unit-wide activities and process improvements (e.g. attending working groups, reviewing Standard Operating Procedures (SOPs) and sharing best practice) ▪ Adhering to appropriate trial regulations and procedures to ensure conduct of the whole life cycle of the trial	
2	**Operational Support:** To provide operational support to the Trial Manager and wider team to help ensure the smooth running of the trial. This will include: ▪ Recruiting and providing on-going information and support to participants ▪ Following up with participants ▪ Ensuring the site meets its recruitment and follow-up targets and report any issues to the Trial Manager ▪ Being responsible for local site coordination and reporting of site performance back to the NCTU ▪ Printing, sending and tracking of trial materials to trial sites and / or participants ▪ Taking responsibility for local site coordination including preparing and maintaining trial files and documentation ▪ Arranging and coordinating trial-related meetings and documentation including taking and writing of meeting minutes ▪ Liaising with trial centres, participants, colleagues and third party providers (email and phone) ▪ Assisting with monitoring of trial budgets and performing financial reconciliation activities	25%
3	**Data Support:** To provide research specific data entry / data validation support: ▪ Working in accordance to the trial data management plan and associated documents ▪ Ensuring timely entry and management of trial data ▪ Ensuring quality of trial data ▪ Working collaboratively with other members of the trial team to identify and resolve data issues in a timely manner in accordance with trial documents	20%
4	**Project Management** ▪ Contributing to the development of a project plan as appropriate for the project ▪ Adhering to project timelines ▪ Tracking/monitoring of project progress in accordance to project plan and needs of the trial escalating issues to the Trial Manager as appropriate	15%
5	**Other** ▪ Any other duties appropriate to the grade and role of the post holder ▪ We recognise the importance of continuous professional development and therefore the importance of providing opportunities, structured support and encouragement to engage in professional development each year	

Person specification

	Essential	Desirable
Skills	▪ Excellent computer literacy skills particularly in using Microsoft applications (Word, Excel and Outlook) ▪ Excellent organisational skills ▪ Good time management skills to prioritise and flexibly manage own workload and work with minimal supervision ▪ Ability to use own initiative ▪ Excellent communication skills both written and oral ▪ Ability to work alone, as well as part of a team ▪ Ability to work under pressure and to deadlines ▪ Excellent attention to detail ▪ Excellent team player ▪ Demonstrate a critical and intelligent attention to detail and high standards of accuracy ▪ Able to interpret clinical/non-clinical data and events to input accurate information	▪ Excellent presentation skills ▪ Self-motivated and able to motivate and influence others within a multi-disciplinary team from a range of professional backgrounds and levels of seniority ▪ Demonstrate initiative to deal with challenges ▪ People management skills ▪ Adaptable and flexible to hours and work ▪ Experience of organising meetings and taking minutes
Knowledge and experience	▪ Experience of working in a research environment ▪ Knowledge of databases ▪ Experience of dealing with members of the public via telephone, email and in person	▪ Experience in clinical trial coordination/ management and track record of successfully completed trials ▪ Working knowledge of Clinical Trial Regulations ▪ Experience of writing proposals and study related documents within a team ▪ Understanding of research approvals (Ethics and NHS approval)
Qualifications, certification and training (relevant to role)	▪ HNC or HND in a relevant subject, or equivalent qualifications /certification, plus considerable experience in relevant role(s) in a research environment	▪ Degree (or equivalent qualification) in a relevant subject or significant experience as a Clinical Trial Administrator ▪ Good Clinical Practice training
Statutory, legal or special requirements	▪ Willingness to travel to UK sites for training, support and monitoring as applicable ▪ 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 friendly, engaging and receptive, putting others at ease. Actively listens to others and goes out of way to ensure people feel valued, developed and supported.
Taking ownership	Is clear on what needs to be done encouraging others to take ownership. Takes action when required, being mindful of important aspects such as Health & Safety, Equality, Diversity & Inclusion, and other considerations.
Forward thinking	Drives the development, sharing and implementation of new ideas and improvements to support strategic objectives. Engages others in the improvement process.
Professional pride	Is professional in approach and style, setting an example to others; strives to demonstrate excellence through development of self, others and effective working practices.
Always inclusive	Builds effective working relationships, recognising and including the contribution of others; promotes inclusion and inclusive practices within own work area.

Key relationships with others