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Role profile

Job title	Monitoring and Quality Manager	Job family and level	Administrative, Professional and Managerial Level 4
School/ Department	School of Medicine - Nottingham Clinical Trials Unit (NCTU)	Location	Nottingham Clinical Trials Unit (NCTU), University Park Campus

Purpose of role

We are a rapidly growing UK Clinical Research Collaboration (UKCRC) registered Clinical Trials Unit (www.ukcrc-ctu.org.uk) based in the School of Medicine at the University of Nottingham. Our mission is to conduct top quality, high impact multicentre clinical trials across a range of health areas which will improve health outcomes. We have a broad and expanding portfolio of trials including studies evaluating pharmacological and non-pharmacological interventions, medical devices, and complex interventions.

The Nottingham Clinical Trials Unit (NCTU) operates a robust Quality Management System (QMS) focused on a suite of standard operating procedures (SOPs) to ensure compliance with regulatory standards within clinical trials. You will support the management and further development of this system and assist in maintaining quality assurance processes to ensure that NCTU continue to meet established standards and regulatory requirements.

The Monitoring and Quality Manager will be a member of the Quality Assurance Team, reporting directly to the Senior Quality Assurance Manager, but will also work closely with other specialities including Trial Management, Data Management, and Statistics to fulfil the monitoring management and trial oversight required of this role. You will support the trial teams in facilitating central and on site management activities relating to the monitoring of clinical trials in addition to the ongoing development and maintenance of the NCTU QMS.

For further information see: http://www.nottingham.ac.uk/nctu/index.aspx

The School of Medicine 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.

To find out more about the School of Medicine, its values, vision, teaching and research, please see our further information leaflet.

	Main responsibilities (Primary accountabilities and responsibilities expected to fulfil the role)	**% time per year**
1	**Monitoring Management** • Provide expert advice to trial teams in ensuring trials have an oversight and monitoring strategy compliant with the relevant SOPs and NCTU QMS. • Work with trial teams in developing a robust monitoring plan which mitigates the risks identified in the risk assessment • Work with trial teams to ensure monitoring is conducted as per the monitoring plan • Lead on the management of central and site-level monitoring processes across the portfolio of trials • Support the planning and conduct of occasional site monitoring visits according to the trial monitoring plan • Support the generation of efficient documentation of site visits including reports, letters etc. • Work with trial teams to resolve discrepancies found during monitoring, addressing any queries raised • Attend Trial Management Group (TMG) meetings as required • Feedback to the appropriate Senior Quality Assurance Manager/Senior Trial Manager/ Senior Data Manager any commonly occurring errors or problems and assist with their resolution	60%
2	**Quality Assurance** • Work closely with the Senior Quality Assurance Manager in further developing, reviewing and maintaining the NCTU QMS • Contribute to writing SOPs and Working Practice Documents (WPDs) • Keep up to date with changes in clinical trial regulations and internationally accepted standards for quality management of clinical trials, and ensure any changes are incorporated into the NCTU QMS • Identify and report any major or critical findings or suspicion of fraud as per NCTU procedures • Provide expertise in governance and regulatory areas of different trials relevant to the NCTU portfolio of work • Answer day-to-day queries from NCTU staff members regarding the NCTU QMS and relevant regulations, providing advice and guidance where necessary	20%
3	**Audit and Inspection** • Lead the conduct and reporting of internal audits at NCTU, in accordance with the NCTU audit programme and relevant SOPs • Provide summary audit reports and discuss recommendations for improvements in practice with the Senior Quality Assurance Manager • Undertake quality control checks of trial documentation to ensure internal coherence and compliance with Good Clinical Practice (GCP)	10%

	• To support the Senior Quality Assurance Manager in preparing for and hosting any external audits and inspections (e.g. from Sponsors or regulatory bodies)	
4	**Training** • Act as point of contact and deliver training in all aspects of monitoring within NCTU, including, but not limited to, NCTU mandatory training. • Provide training to NCTU staff on regulatory, ethical and governance developments in clinical trials and as part of the SOP training programme • Contribute to the development and maintenance of a comprehensive SOP training programme for NCTU staff members • Support the Senior Quality Assurance Manager and Line Managers, in maintaining oversight of mandatory training within NCTU as per NCTU SOPs	10%
5	**Other** • Work flexibly to provide cover for members of the team during period of absence • Any duties as required in accordance with the nature and grade of the post	N/A

Person specification

	Essential	**Desirable**
Skills	• Ability to communicate and work effectively with colleagues • Ability to work both independently and as part of a multidisciplinary team • Evidence of being self-motivated, organised, and able to take appropriate responsibility • Excellent ability to prioritise, and to work flexibly and effectively under pressure • Able to manage workload in a demanding and challenging environment • Excellent MS Office skills (Excel, PowerPoint and Word) • Excellent written and oral communication skills • Excellent attention to detail	• Skilled in conducting and writing audit reports, with findings and actions • Skilled in writing monitoring reports and the generation of monitoring documentation

Knowledge and experience	• Demonstrable experience in clinical trial monitoring • Up to date knowledge and understanding of Clinical Trial Regulations, and research governance guidelines • Comprehensive understanding of trial design, trial conduct and trial delivery • Experience of developing and/or maintaining Quality Management Systems, including writing SOPs and related documents	• Evidence of formal training in monitoring for clinical trials • Experience of reviewing monitoring plans and risk assessments • Extensive knowledge of all regulations and guidelines relating to clinical trials (e.g. medical devices, advanced therapeutics) • Experience of delivering training • Experience of MHRA and sponsor audits / inspections
Qualifications, certification and training (relevant to role)	• Relevant degree or professional qualification OR • Proven track record of extensive relevant work experience demonstrating practical and theoretical knowledge of quality assurance and monitoring management in a clinical research environment	• Postgraduate/professional qualification in clinical research or similar
Statutory, legal or special requirements	• Travel within the UK may be required on occasion for monitoring purposes and attendance at meetings • 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