

Job title	Senior Data Manager	Job family and level	Administrative, Professional and Managerial Level 5
School/ Department	School of Medicine, Nottingham Clinical Trials Unit	Location	University Park Campus

Purpose of role

To lead the Nottingham Clinical Trials Unit's (NCTU) data team in providing clinical research databases and data capture tools that are fit for purpose, meet regulatory requirements, and facilitate efficient and high quality research. As part of the unit's multidisciplinary operations team, the role holder will play a vital part in planning and delivering the unit's portfolio of clinical trials. The role holder will maintain and further develop systems for capturing and managing clinical trial data, develop best practice, deliver training, review NCTU requirements for data management on an ongoing basis, and provide advice and support to the Director about all issues relevant to data management. The role holder will foster and develop key relations with University Information Services, research collaborators, and external organisations such as NHS Trusts and other clinical trials units. The role holder will have line management responsibility for a team of database systems developers and data managers and will oversee their day-to-day work.

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

NCTU has a broad portfolio of trials including studies evaluating drugs, devices and complex interventions. Particular strengths are trials of dermatology, reproductive health and childbirth, gastroenterology, respiratory medicine, stroke, mental health, surgery (particularly hand surgery), and genitourinary medicine. Other research includes methodological studies to improve the efficiency and quality of trial conduct, and systematic reviews and meta-analysis.

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

	Main responsibilities (Primary accountabilities and responsibilities expected to fulfil the role)	% time per year
	The role holder will lead a team of database systems developers and data managers to meet the operational requirements of the unit with respect to capture and management of clinical research data. This will include line managing team members, overseeing day to day work, and maintaining a positive and cohesive work environment in order to maximise effective working across the unit's	

	<p>multidisciplinary teams. The work of the team, and that of the role holder, is focused within the areas detailed below:</p>	
1	<p>Information systems, database development and maintenance</p> <ul style="list-style-type: none"> ▪ Plan and oversee high quality and timely development of databases and data capture tools for all new trials, including data specifications, validation definitions and data management plans. ▪ Work closely with other members of the operations team to agree timelines for new trial databases, regularly review progress and take appropriate action to maintain agreed schedule. ▪ Specify data team deliverables for each study and ensure these are achieved; review and adjust resource allocations as required from study start-up through to archiving. ▪ Work closely with the University's Information Services department to ensure appropriate monitoring and support of NCTU IT systems and platforms, managing change and planning for future capacity. ▪ Horizon scan to identify new technology requirements relevant to data management and database systems, and brief colleagues on their relevance to the unit. Plan and oversee the development and implementation of any new technology. ▪ Advise senior NCTU colleagues about strategic developments relevant to data management, including regulatory requirements, confidentiality and data sharing. 	40%
2	<p>Data management and project management</p> <ul style="list-style-type: none"> ▪ Specify resource requirements for research funding applications, including costing and timelines for paper/ electronic case report form (CRF) development, database build and validation, data processing and on-going review and quality control. ▪ Review trial protocol amendments; conduct impact and risk assessment to ensure that all relevant data management functions are maintained. Ensure updates to databases and data capture tools are performed within agreed timelines. ▪ Oversee the development, implementation and compliance with standard operating procedures (SOPs) for collecting and managing clinical research data. In consultation with the unit's Quality Assurance team, update SOPs in response to changing regulatory requirements (clinical trial and data protection), good clinical practice (GCP) standards, ethics guidance, safety reporting and other relevant guidance. 	40%

	<ul style="list-style-type: none"> ▪ Lead the data team's participation in internal audits and statutory inspections by the Medicines and Healthcare products Regulatory Agency (MHRA). ▪ Assess the overall quality of data; establish and implement metrics to identify any issues, trends or patterns that may threaten overall study quality or compliance with regulations. ▪ Monitor compliance with data management plans, including training staff, regular reviews, and implementing effective strategies to enhance compliance. ▪ Work proactively with other members of the operations team to identify and address emerging issues within and across studies, producing regular status reports and ensuring day-to-day operations are maintained. ▪ Escalate, when appropriate, issues related to data management processes, timelines, resourcing, performance, etc. with proposed solutions, to the operations team, and when necessary to the Director / Deputy Director. 	
3	<p>Training</p> <ul style="list-style-type: none"> ▪ Develop materials and deliver training to the data team, and to other members of academic, research and support staff as appropriate. ▪ Provide day-to-day guidance and support to NCTU staff in aspects of data management. 	15%
4	<p>Any other duties as appropriate to the role and level</p> <ul style="list-style-type: none"> ▪ In discussion with the Director/ Deputy Director, any other duties appropriate to the role and level that assist in delivering the unit's strategic plan. 	5%

Person specification

	Essential	Desirable
Skills	<p>Extensive and up to date understanding of regulations and guidelines applicable to IT and data management.</p> <p>Excellent organisational skills, ability to prioritise tasks to meet deadlines, and demonstrable track record of excellent project management</p> <p>Proven leadership and management skills</p>	<p>Training and experience in MedDRA coding</p> <p>Knowledge of the Clinical Data Interchange Standards Consortium (CDISC)</p> <p>Excellent SQL skills</p>

	<p>Demonstrable ability to successfully coach/mentor others</p> <p>Excellent verbal and written communications skills</p> <p>Excellent report writing skills including experience in developing systems for monitoring and reporting on data management</p>	
Knowledge and experience	<p>Extensive experience of database programming, including database setup, data import/export, data manipulation, data reporting and data archiving.</p> <p>Experience of developing data collection forms, data management plans, and data specification and validation plans</p> <p>Knowledge and experience of applying regulations that govern data collection and management for example Good Clinical Practice.</p> <p>Evidence of being an effective leader of a multidisciplinary team of technical and non-technical staff</p> <p>Experience of planning and monitoring resource requirements, and setting and adhering to realistic timeframes for project completion</p>	<p>Experience of data management in randomised clinical trials or clinical research in either an academic or commercial setting.</p> <p>Expertise in server administration & maintenance.</p> <p>Experience of using database systems such as MACRO, OpenClinica, REDCap, Oracle Clinical, or Clintrials to manage clinical research data</p> <p>Experience of statutory inspection and audit by regulatory authorities such as the MHRA</p> <p>Experience of writing business cases for new technologies</p> <p>Experience of working with third party data providers, such as central laboratories.</p> <p>Experience of working with third party system vendors.</p>
Qualifications, certification and training (relevant to role)	Relevant degree or professional qualification plus significant experience in a similar role	Postgraduate qualification in IT/Computer Science or a related field



The University 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.

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



