

Job title	Data Coordinator	Job family and level	Administrative, Professional and Managerial Level 3
School/ Department	School of Medicine, Nottingham Clinical Trials Unit (NCTU)	Location	The East Midlands Campuses of the University of Nottingham

## Purpose of role

The purpose of the role is to support a consistent approach to coordinating data handling and quality across a number of clinical trials. You would be responsible for collaborating on the development of clinical trial databases, coordinating and performing data reviews, data validation and quality procedures and implementation on NCTU managed research. You will be responsible for the training and supervision of data administrators. You will work closely with Investigators, Trial Managers, and the Data Managers to ensure high clinical research data quality.

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 100 staff, and with the recent investment of strategic development funding from the University this is anticipated to expand to 120 staff over the next 3-5 years.

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

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 <u>further information leaflet</u>.

	Main responsibilities (Primary accountabilities and responsibilities expected to fulfil the role)	% time per year
1	<ul> <li>Database and Documentation</li> <li>Work with multidisciplinary teams in the development of data management documentation, including but not limited to: Case Report Forms, study specific Data Management Plans, Data Validation Documents and Data Entry Guidelines. Lead in the maintenance of this documentation in line with study requirements</li> </ul>	30%

	<ul> <li>for the duration of the study. Continuously seeking ways to improve data completeness and data quality.</li> <li>Work with the Database Systems Developer to design and build the trial database within REDCap system.</li> </ul>	
2	<ul> <li>Data Delivery</li> <li>To manage and/or perform the review of study data to ensure data is collected in a timely manner, is complete and is of a high standard.</li> <li>Collate metrics and provide feedback on common issues to the trial management team.</li> <li>During study lifecycle meet regularly with clinical trial teams to monitor data activities and advise on data management related tasks.</li> </ul>	30%
3	<ul> <li>User Acceptance Testing</li> <li>To perform and/or coordinate the user acceptance testing of the clinical database(s), in order to provide feedback to the database system developers.</li> </ul>	10%
4	<ul> <li>Data tracking</li> <li>Oversight and management of the tracking of data on clinical trials, including reconciliation of forms prior to database lock.</li> </ul>	10%
5	<ul> <li>Supervision Responsibilities</li> <li>Supervision as appropriate of Level 2 data administrator(s). Supervision to include:         <ul> <li>Allocating work and monitoring against deadlines.</li> <li>Manage and prioritise activities to ensure timely delivery of study data.</li> </ul> </li> </ul>	10%
6	<ul> <li>Coding and Quality Control</li> <li>To perform coding of medical terms.</li> <li>Oversees the QC of the clinical data and additional data cleaning as required. Make any recommendations for improvements to data guidelines.</li> </ul>	10%
7	<ul> <li>Other</li> <li>Any other duties appropriate to the grade and role of the post holder.</li> </ul>	N/A

## Person specification

	Essential	Desirable
Skills	<ul> <li>Good interpersonal and communication skills both written and spoken</li> <li>Ability to communicate data issues to others within a multi-disciplinary team from a range of professional backgrounds and levels of seniority</li> <li>Keyboard/typing skills</li> <li>Detail oriented</li> <li>Good organisational skills</li> <li>Assessing and responding to non- routine work/situations</li> <li>Ability to work both unsupervised and as part of a team</li> <li>Ability to train and monitor others</li> <li>Ability to prioritise and delegate work to meet deadlines</li> <li>Good time management</li> <li>Ability to build working relationships with senior staff</li> </ul>	<ul> <li>Advanced Microsoft Word and/or Excel skills</li> <li>REDCap database skills</li> </ul>
Knowledge and experience	<ul> <li>High level of IT skills (MS Office, Excel) particularly the use of Email, MS word</li> <li>Knowledge of Good Clinical Practice</li> <li>Knowledge of clinical trials, and clinical trial databases management systems</li> <li>Working experience of data reviewing/validation processes in relation to clinical trials</li> <li>Experience of data capture form design</li> <li>Experience of writing data management plans and data entry guidelines</li> <li>Experience of writing or reviewing data validation documentation</li> <li>Prior use of Clinical trial databases</li> <li>Experience of performing user testing</li> </ul>	<ul> <li>Previous experience of clinical trials and/or their data entry</li> <li>Experience of Clinical Coding</li> <li>Experience of Case Report Form design on clinical trials</li> <li>Liaised previously with recruiting site staff</li> <li>Experience working with 3rd party data providers, such as central labs or routine data providers such as Office of National Statistics or National Health Service digital</li> <li>Has performed User Acceptance Testing for a clinical trial database setups</li> <li>Prior exposure to Remote Data Entry/electronic Case Report Form</li> <li>Working knowledge of participant follow-ups via questionnaires paper and/or on-line</li> <li>Familiar with web based applications</li> <li>Working knowledge of data manipulation software, e.g. STATA or SAS</li> <li>Ability to produce summary data report and line listings</li> </ul>
Qualifications, certification and	<ul> <li>HNC or HND in a relevant subject, or equivalent</li> </ul>	<ul> <li>Significant experience as a Data Coordinator or equivalent position</li> </ul>

training (relevant to role)	qualifications/certification, or considerable experience in a relevant role(s)	<ul> <li>Degree (or equivalent qualification) in a relevant subject</li> </ul>
Other	<ul> <li>Adopting and delivering to the School of Medicine's Professional Services Service Excellence Standards</li> <li>Willingness to adopt the <u>vision</u> <u>and values</u> of the School of Medicine</li> </ul>	



## 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

