

Job title	Database Manager	Job family and level	Administrative, Professional and Managerial Level 4
School/ Department	School of Medicine, Translational Medical Sciences	Location	Clinical Sciences Building, City Hospital Campus

Purpose of role

The main purpose of the role is to support the NIHR Nottingham Respiratory Biomedical Research Centre (BRC) in leading the data management specialist activities such as design, set-up, programming and management of computerised databases for the capture and management of data across a portfolio of clinical, alongside maintaining data capture/monitoring tools to support the Nottingham Respiratory BRC reporting process.

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	 Data management Activities Be responsible for the leading the data management specialist activities such as design, set-up, programming and management of computerised databases for the capture and management of data across a portfolio of clinical trials of the Respiratory BRC and Respiratory Investigator Lead Trials. Be responsible for completing the specialist processes to ensure the maximum quality of the data (including data validation and quality control) and will be responsible for the delivery of data suitable for statistical analysis Undertake basic data analysis and generate complex data queries for preparing required internal and external reports Be the specialist for preparing and delivering internal and external training on data management and use of study databases. Work closely with the research team members to ensure appropriate data collection and to design data collection forms Perform regular, systematic checks to validate and verify information on the database(s) in order to produce a clean, accurate and complete data set for analyses. 	35%

	 Oversee the maintenance and management of current HTA Tissues database application. 	
2	 Support the Respiratory BRC in maintaining metrics for NIHR Reporting Contribute to BRC reporting and project Dashboard updates by ensuring Clinical Trial Data Management System and other tools updated weekly for projects, recruitment figures Contribute to BRC reporting by using SCOPUS, PUBMed and other tools to ensure publications kept up to date in reporting tools Assist in the preparation of data and materials for publication and/or presentation at scientific meetings or in scientific journals. To assist in the production of newsletters, posters and trial summaries for scientific meetings. 	35%
3	 Project Management To project manage quality control and data validation process for trial databases. Work closely with the study sites and the research team to monitor, raise and resolve data queries. Ensure the smooth day-to-day management of data collection and data entry and processing in accordance with ICH GCP and as specified in the study protocol. 	10%
4	 Governance/Education and Training Prepare and deliver appropriate training for research staff in the use of study database, electronic data capture systems and data management activities according to CFR 21 Annex 11, ICH GCP / ACDM. Monitoring and maintaining data security in line with data protection regulations. 	10%
5	 Other requirements of the role Set-up and maintain the appropriate randomisation system for a randomised controlled trial. Work closely with the research delivery staff to develop the randomisation list and system. Link the randomisation system with the study database, where appropriate. Attend internal and external meetings as the expert in database management and develop close and effective working relationships with Chief Investigators, Principal Investigators, statisticians, PhD students and trial management staff. Dissemination of specialist knowledge/technical skills to other colleagues where required. Ability to escalate problems with the appropriate staff at the relevant time. To assist in the induction of new staff, research fellows and PhD students, providing support within the research team. The Nottingham Respiratory BRC is a partnership with Nottingham University Hospitals Trust. The post holder will also be expected to support NUH staff within the Respiratory BRC in maintaining the Nottingham Respiratory Volunteer register, text service and any other requests relating to delivery of a study. 	10%
6	 Any other duties appropriate to the grade and role. 	N/A

Person specification

	Essential	Desirable
Skills	 Demonstrable skills in the production and deployment of electronic data capture software. Demonstrable skills creating and maintaining websites. Communicates complex data management activities and procedures with health care professionals, researchers, administrative staff and users of the health service authority. Able to work effectively within and across clinical teams both internal and external. Ability to present complex technical concepts in a clear manner. Ability to work in a team environment, supporting colleagues and sharing expertise. Ability to analyse, investigate and resolves complex data queries and issues. 	 Ability to identify new opportunities and creative solutions. Undertakes data analysis and quality control. Supports on data management activities which support a portfolio of clinical trials. Ability to provides a randomisation service for clinical trials.
Knowledge and experience	 In depth experience as Data Manager (or equivalent) on clinical trials. Experience of data collection in a research context / database design / managing large datasets. Experience of data validation, analysis and reporting. Experience to query and maintain databases. Substantial knowledge of clinical trials and research. Sound knowledge of clinical trial methodology. Experience of interpreting complex information to produce and distribute reports, summaries, worksheets and statistics. Previous administrative experience. Experience of dealing with confidential issues. Relevant previous Database creation and management experience. 	 Experience of respiratory clinical research/trials. Knowledge of HRA approval process. Proficient and experienced in configuring and use of electronic data capture software (e.g. Medrio, REDcap etc). Experience of troubleshooting software and hardware issues. Knowledge of creating and maintaining websites.

Qualifications, certification and training (relevant to role)	 Degree or equivalent in a relevant technical subject OR substantial training and experience in a similar role. 	 Governance and regulations (e.g. ICH-GCP and EU Directives). Training and full understanding of 21 CRF Annex 11 for clinical trials databases and management.
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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

