JOB DESCRIPTION

Job Title
Data Manager

Position Number
52370045 & 52534219

Academic / Service Unit
Newcastle Clinical Trials Unit

Effective Date

Grade **Vacancy Ref**
F A115065A

Faculty / Central Services
Faculty of Medical Sciences

Main Purpose

You will work with Chief Investigators, trial teams, database providers and others as appropriate to ensure the smooth running of all data aspects of NCTU trials. They will be responsible for the design, set-up, programming and management of computerised databases for the capture (including electronic remote data capture and randomisation systems) and the management of data within these, across a portfolio of clinical trials. You will be responsible, with trial managers and trial statisticians, for identifying processes to ensure the highest level of data integrity and will be responsible for ensuring data are suitable for statistical analyses. These systems and data will meet the quality standards expected for reporting to regulatory bodies and in accordance with all applicable legislation, and Good Clinical Practice guidelines. They will be proactive in their approach to work.

Main Duties and Responsibilities

1. Design, develop, test, and maintain databases and data capture systems for clinical trials documenting each element in line with relevant SOPs using one or more proprietary Clinical Data Management System packages (e.g. MACRO, Red Pill).
2. Design, develop, test, and maintain randomisation systems for clinical trials documenting each element in line with relevant SOPs using one or more systems (e.g. Sealed Envelope).
3. Design, develop, test, and maintain other databases (e.g. ACCESS) to support the administration of clinical trials
4. Enable accurate, complete and timely entry of all study data
5. Work closely with the trial management group in contributing to the design of data collection forms
6. Oversee the collection and collation of data collection forms from participating centres and ensure the input of this data onto computerised databases as needed
7. Work closely with the trial manager and trial statistician to perform regular and timely data cleaning procedures, and quality controls to ensure that all trial data are accurate, complete and timely, identifying and following up any data omissions or queries, identifying potential problems and taking appropriate action
8. Ensure good working relationships between NCTU and its clinical, academic and other partners and collaborators.
9. Prepare data for analysis as required by the statistician including coding as required (e.g. MedDRA)

10. Prepare data management plans and ensure accurate and thorough documentation of all data management activities in accordance with applicable legislation and current standard operating procedures
11. Provide data to the Trial Management Group to facilitate the preparation of progress reports for Funders, Ethics Committees, Trial Steering Committees, Independent Data Monitoring and Ethics Committees, and other bodies, performing basic descriptive analyses of data, and presenting results in a format suitable for reporting.
12. Assist in the preparation of data and materials for publication and/or presentation at scientific meetings or in scientific journals
13. Give presentations and provide training on the effective use of data capture systems including development of trial specific user manuals
14. Ensure studies are conducted in accordance with GCP and other applicable legislation for Clinical Trials, and the Data Protection Act
15. Ensure secure protection of all databases to ensure that inappropriate access does not occur and ensure maintenance of confidentiality of all information obtained and held within the department for trial purposes.
16. Ensure secure back up of all trial data
17. Contribute to, and lead on, writing and reviewing of SOPs and policy documents on data collection and management systems and processes, including the review of quality improvement and other related initiatives.
18. Contribute to internal NCTU staff training regarding data collection management systems, randomisation systems and processes
19. Any other duties, appropriate to the grade, which may be required from time to time by the NCTU

Dimensions

There are currently approximately 50 active trials being conducted by NCTU. NCTU works with multiple trial sponsors, locally, nationally and internationally and from two main hubs in Newcastle and South Tees. Chief Investigators, Principal Investigators, and Co-Investigators are located throughout and beyond the University. You will be expected to work at both sites depending on the needs of individual trials and NCTU.

Planning and Organising

Be able to plan and organise own workload and supervise that of Database Officers when required.
Assist Chief Investigators in planning data collection systems

Decision Making

Will be required to make independent decisions and advise on the decisions of Database Officers. Expected to be able to work largely on own initiative while being aware of circumstances which require the involvement of CIs, trial statisticians and trial managers.

Internal and External Relationships

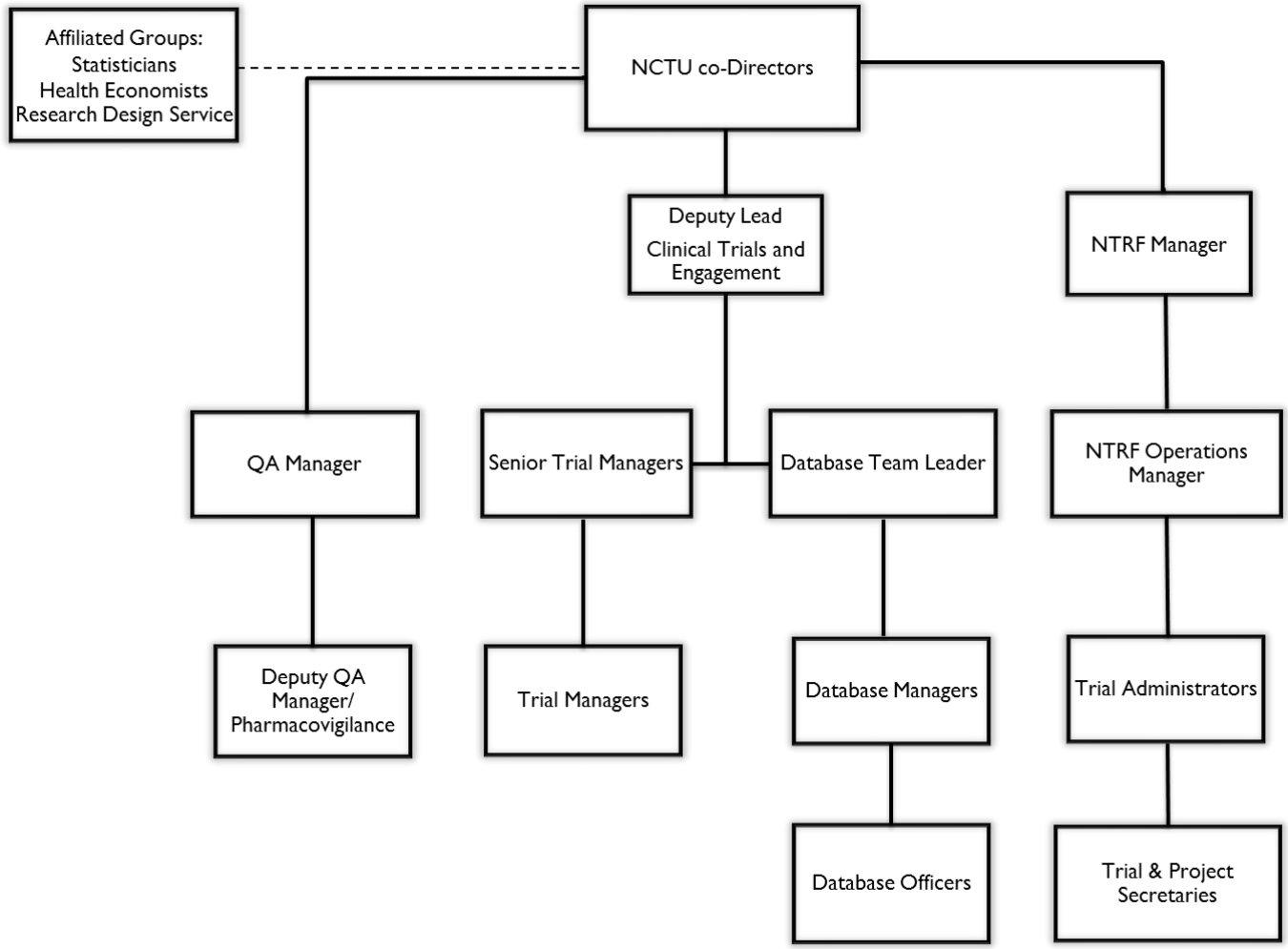
Work closely with Medical Sciences Faculty, NHS and academic collaborators and trial site staff. Expected to supervise the work of Database Officers.

Attend internal and external meetings as the expert in database management and develop close and effective working relationships with CIs, PIs, statisticians, health economists, other specialists, and trial management staff.

Other Relevant Information

Excellent communication skills, excellent organisational and administrative skills

Organisation Chart



Person Specification
Knowledge (inc. qualifications)

Essential
- Degree in a relevant subject (or equivalent relevant experience)

Desirable
- Higher degree in a relevant subject

Skills (professional, technical, managerial, practical)
Essential

- High levels of literacy and numeracy
- Knowledge of good data management principles
- Evidence of ability to set up, maintain and manage an effective research data management system, which produces reports and raises queries, e.g. web-based CRF
- Excellent IT skills including the use of the Microsoft Office package
- Excellent interpersonal skills
- Excellent attention to detail
- Ability to prioritise and work independently, proactively, quickly and accurately to deadlines
- Excellent organisational ability
- Ability to take responsibility, prioritise and manage workload using your initiative as required
- Ability to work effectively in a team
- Working knowledge of regulatory and governance requirements for clinical trials in the UK. An understanding of the requirement of data protection regulations, the need for confidentiality and the ability to work to these.

Experience and Achievements (paid or unpaid)
Essential
- Experience of database design
- Experience of data management, data checking, and reporting

Desirable
- Knowledge and hands-on experience of statistical software
- Knowledge and hands-on experience of SQL programming
- Knowledge and hands-on experience of Clinical Data Management Systems (e.g. MACRO)
- Knowledge of Clinical Trial Methodology
- Experience of data analysis
- Experience of working on an interventional clinical trial
- Experience of working in a University or NHS environment

- An understanding of data collection in an NHS environment

Other

Essential

- Flexible approach to working
- Willingness to travel to trial sites and to trial meetings as required.
- Willingness to work at each of the two NCTU sites located in Newcastle and at South Tees Hospitals NHS Foundation Trust

Behaviours (Success Factors)

Name *Typical Behavioural Indicators*

Taking responsibility	**Finding Solutions** Generates a range of viable options and decides on an appropriate course of action that best fits organisational and area goals. • Formulates options and possible scenarios for consideration • Confidently deals with a broad range of information
Working Together	**Team Working** Works collaboratively with others, plays a positive role in teams and establishes and grows relationships across the organisation where different skills, expertise and opinions are valued. • Shares relevant and useful information • Willing to help others and share workloads • Respects the value that different views bring to the team
Looking to the Future	**Thinking Strategically** Has the ability to see the big picture, to think strategically and manage complex problems and issues • Uses analytical techniques to break down complex problems into component parts • Anticipates obstacles and thinks ahead to next steps
Inspiring Others	**Communicating** Uses clear, concise and accurate communication, tailoring the approach accordingly and encouraging a two way communication process.

	• Can put forward own view while listening and respecting the views and opinions of others • Tailors content of communication to the audience, changing style, tone and format appropriately