Royal Devon University Healthcare NHS Foundation Trust

JOB DESCRIPTION

JOB DETAILS	
Job Title	Clinical Research Data Manager
Reports to	Clinical Research Manager
Band	5
Department/Directorate	Research and Development

JOB PURPOSE

To lead a team of Data Assistants, providing administrative support to the Clinical Research Teams in order to ensure that:

- Research pathways are efficient
- Research study specific targets are met
- Research High Level Objectives are met

To deputise for the Clinical Research Managers required.

KEY RESULT AREAS/PRINCIPAL DUTIES AND RESPONSIBILITIES

The post holder will contribute, provide feedback and undertake presentations to monthly or quarterly Trust Research Meetings as required e.g. Governance and Oversight Group, Clinical Trials Team Lead Meeting, Delivery Team Meetings.

Liaising with the Clinical Research Manager and other Team Leads, the post holder will identify where user training is required within delivery teams, and if appropriate provide that training on the Research Databases: e.g. EDGE and study specific electronic data capture systems.

The post holder must be able to sufficiently explain complex data issues to colleagues and Sponsors, such as criteria used, the method of extraction and source of data, trends and outliers, data quality issues, and the context the information should be viewed in such as a change in process or how services are delivered.

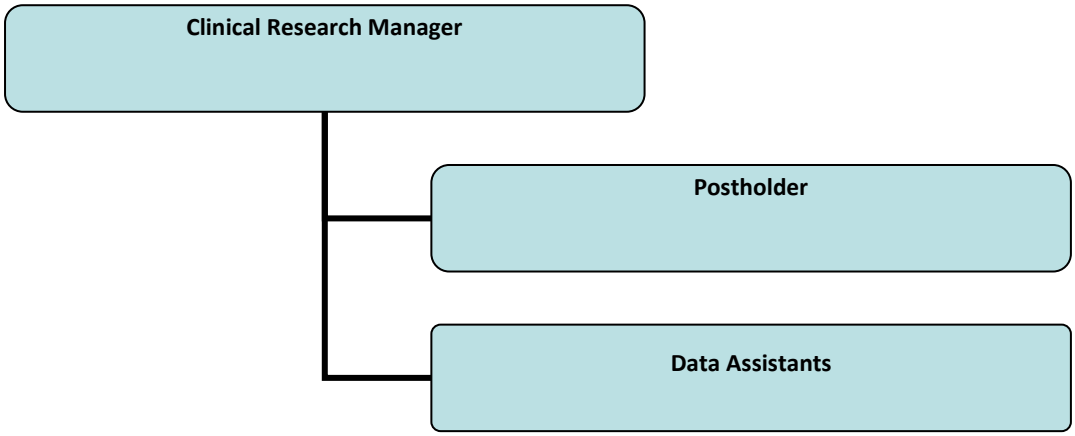
The post holder will fulfil all tasks and work as part of a team. To meet the needs of the service, the post holder may be required to work in other areas as appropriate as directed by the line manager.

KEY WORKING RELATIONSHIPS

The post holder is required to deal effectively with staff of all levels throughout the Trust as and when they encounter on a day to day basis.
In addition, the post holder will deal with the wider healthcare community, external organisations and the public.
This will include verbal, written and electronic media.
Of particular importance are working relationships with:

Internal to the Trust	External to the Trust
• Clinical Research Manager • Data Assistants • Clinical Delivery Teams • Clinical Delivery Team Leads • Research Professional Services Teams • IT Services • Study Principle Investigators and Chief Investigators • Chief Research Information Officer • EPIC Team	• Study Sponsors • Clinical Trials Unit • University of Exeter • Commercial Partners

ORGANISATIONAL CHART



FREEDOM TO ACT

The postholder will act independently, guided operational policies, managing own workload and referring to line manager when appropriate.

COMMUNICATION/RELATIONSHIP SKILLS

The post holder will communicate with all levels of personnel within Health Organisations by providing and receiving complex, sensitive and contentious information e.g. providing health information to commercial and non-commercial partners for patients enrolled in clinical trials, alerting and guiding users of the hospital systems of incorrect data entry which impacts on minimum datasets, government set targets (e.g. recruiting time to target).

ANALYTICAL/JUDGEMENTAL SKILLS

The postholder will need to be able to incorporate validation and reconciliation of work as a built-in working process. Specifically: establishing checking mechanisms e.g. checking totals, scanning information for outlying figures, comparing one data source against another, looking at the source data for anomalies and missing data items, looking at data over a period of time and investigating extreme variances.
In conjunction with Information Services and EPIC, they will collate and compile data reports, both requested and standard, relating to clinical trials patients and database completeness and feed these reports back to delivery teams and Sponsors.
They will require a degree of competency in using a range of software tools for data extraction from hospital systems and subsequent analysis and presentation.
They will work with the Clinical Research Manager and Research Information analysts understand research data requirements including study specific datasets and databases (e.g. EDGE, CPMS) and ensure that completeness/accuracy is maintained across the Trust.
In conjunction with Information Services, they will collate and compile data reports, both requested and standard, relating to all research patients and database completeness and feed this back to the relevant teams or Sponsors.

PLANNING/ORGANISATIONAL SKILLS

The Data Manager's s role is an essential part of the smooth running and efficiency of data collection strategy as per study protocol. This post is designed to act as the key support for all the data assistants, in terms of organising and supporting their workload, ensuring timely and accurate collection of necessary data and covering MDTs in person when required. Key tasks are:

- To organise and manage cover arrangements for the team, taking an active role in those arrangements so that a familiarity with all research delivery teams s is maintained.
- To organise and monitor training for the team as required.

- To work with the data assistants and delivery teams to ensure that data items pertinent to patient pathways and study protocols are collected and monitored.

The post-holder will need to plan and organise own work schedule with the use of appropriate planning aids, demonstrating good time management and ensuring anticipated difficulties in meeting deadlines are promptly reported.
The post-holder will need to adhere to deadlines, specifically those that are determined by the Department of Health for mandatory returns, and internally by the Trust for business-critical analysis. They will need an awareness of current targets and Trust goals, particularly in relation to key performance indicators.

PATIENT/CLIENT CARE

The post-holder will have no direct responsibility for patient care, but will lead a team responsible for ensuring correct recording of patient care and outcomes for clinical trials, which will feed directly into external datasets and can sometimes feed directly into National Datasets.
The post-holder's team is also responsible for tracking patients through the research pathways, ensuring that pathways are efficient and identifying any blocks in processes that may be detrimental to the pathway and could incur protocol deviations or impact on patient experience.

POLICY/SERVICE DEVELOPMENT

The post-holder will ensure that local and national research dataset requirements are delivered to the required standard and quality.

To do this they will become familiar with all research data collection systems across the Trust and study specific databases and will lead the development of robust information systems to support data assistants and wider research delivery teams. This will include some patient pathway improvement work, in order to ensure that pathways for research patients are efficient and appropriately monitored.

The post-holder will provide advice to the Trust's clinical teams in interpreting and implementing national Research datasets and study requirements -– this involves interpreting, advising and contributing towards documents as well as local plans and monthly meetings.

FINANCIAL/PHYSICAL RESOURCES

The post-holder will have no direct budgetary responsibility but will work with the Clinical Research Manager to ensure that the departmental budget is monitored, assisting in the checking of staff timesheets, expenses claims and oracle orders

They will be responsible for the everyday use of the Trust's data collection Equipment (including video-conferencing equipment), ensuring that users are sufficiently trained in its safe use and that technical issues are properly reported to the equipment provider in a timely manner in accordance with the system's maintenance contract.

HUMAN RESOURCES

The post-holder will have day to day line management responsibilities of the following staff:

- Data Assistants

This includes:

- Work allocation
- Managing leave requests
- Training and development
- Performance appraisals
- Sickness monitoring
- Initial stages of grievance and discipline

INFORMATION RESOURCES

The post-holder will work with the Data Assistants, Lead Clinicians and Clinical Delivery Teams to ensure that information entered onto the local and study specific data capture systems is of the highest quality and validity.

They will work with the Clinical Research Manager and Research Professional Services to understand national research data requirements including EDGE and ODP and ensure that completeness/accuracy is maintained across the Trust.
They will ensure that all data is collected and managed appropriately, and in accordance with the Trust's Information Governance policies and the Data Protection Act.
They will ensure that secure systems are in place for the storage of all resources, including computerised information.
They will ensure that all data is collected and managed appropriately, and in accordance with the Trust's Information Governance policies and the Data Protection Act.
They will support the Clinical Research Manager in preparation of research delivery reports and Trust performance reporting.
They will support the Clinical Research Manager in preparation of information required for efficient Trial delivery.
They will work with the Clinical Research Manager and the Quality Assurance Team in ad-hoc Service Improvement Projects.
They will deputise for the Clinical Research Manager at meetings (both internal and external) when required

RESEARCH AND DEVELOPMENT

Comply with Trust's and R&D department requirements and undertakes regular data integrity checks as necessary to own work.

PHYSICAL SKILLS

Utilisation of advanced keyboard skills for operation of a wide range of computer software and manipulation of data for reporting purposes.

PHYSICAL EFFORT

There is a frequent requirement for sitting or standing in a restricted position for a substantial proportion of the working time. There may be a requirement for light physical effort when using equipment such as projectors.
Ability to lift/carry case notes and move them across the hospital site by use of a notes trolley once or twice a week on average.

MENTAL EFFORT

There is an occasional requirement for prolonged concentration for checking data and documents, writing reports, analysing statistics.

EMOTIONAL EFFORT

Exposure to distressing or emotional circumstances is rare, however the post holder may have difficult or challenging conversations with staff.

WORKING CONDITIONS

Office conditions and may use VDU more or less continuously on most days.

OTHER RESPONSIBILITIES

Take part in regular performance appraisal.

Undertake any training required in order to maintain competency including mandatory training, e.g. Manual Handling

Contribute to and work within a safe working environment

You are expected to comply with Trust Infection Control Policies and conduct him/herself at all times in such a manner as to minimise the risk of healthcare associated infection

As an employee of the Trust, it is a contractual duty that you abide by any relevant code of professional conduct and/or practice applicable to you. A breach of this requirement may result in action being taken against you (in accordance with the Trust's disciplinary policy) up to and including dismissal.

You must also take responsibility for your workplace health and wellbeing:

- When required, gain support from Occupational Health, Human Resources or other sources.
- Familiarise yourself with the health and wellbeing support available from policies and/or Occupational Health.
- Follow the Trust's health and wellbeing vision of healthy body, healthy mind, healthy you.
- Undertake a Display Screen Equipment assessment (DES) if appropriate to role.

APPLICABLE TO MANAGERS

Leading the team effectively and supporting their wellbeing by:

- Championing health and wellbeing.
- Encouraging and support staff engagement in delivery of the service.
- Encouraging staff to comment on development and delivery of the service.
- Ensuring during 1:1's / supervision with employees you always check how they are.

GENERAL

This is a description of the job as it is now. We periodically examine employees' job descriptions and update them to ensure that they reflect the job as it is then being performed, or to incorporate any changes being proposed. This procedure is conducted by the manager in consultation with the jobholder. You will, therefore, be expected to participate fully in such discussions. We aim to reach agreement on reasonable changes, but if agreement is not possible, we reserve the right to insist on changes to your job description after consultation with you.

Everyone within the Trust has a responsibility for, and is committed to, safeguarding and promoting the welfare of vulnerable adults, children and young people and for ensuring that they are protected from harm, ensuring that the Trusts Child Protection and Safeguarding Adult policies and procedures are promoted and adhered to by all members of staff.

PERSON SPECIFICATION

Job Title	Clinical Research Data Manager

Requirements	Essential	Desirable
QUALIFICATION/ SPECIAL TRAINING		
Good general level of education to degree level or equivalent proven NHS background experience	E	
ECDL in computing or equivalent level of experience	E	
KNOWLEDGE/SKILLS		
Familiarity with NHS clinical and information processes and systems	E	
Good working knowledge of medical terminology, preferably clinical trials specific	E	
Awareness and understanding of the data protection act	E	
Awareness and understanding of Good Clinical Practice Guidelines		D
Awareness and understanding of Research Governance Framework		D
EXPERIENCE		
Working knowledge of Trust computerised systems, primarily: EPIC	E	
Expert user of Microsoft Office programmes e.g. Excel, PowerPoint, Outlook	E	
Working knowledge of reporting software packages e.g. EDGE, CPMS	D	
Experience of basic data management processes including implementing quality assurance processes	E	
Experience in collating, analysing and interpreting clinical datasets	D	
PERSONAL ATTRIBUTES		
Communication Skills		
Personal ability to gain influence within the workplace and motivate other people in order to achieve progress	E	
Excellent interpersonal skills in order to work effectively with a wide range of health professionals and as part of a team	E	
Ability to be diplomatic and able to interact with people at all levels, backgrounds	E	
Ability to communicate information both orally and on paper	E	
Skills in report writing, succinct discussion and ability to produce documents.		D
Analytical & Judgement Skills		
An aptitude for highly detailed, accurate work	E	
Ability to deal with sensitive and confidential information	E	
Planning & Organising Skills		
Proactive and well organised	E	
Good team worker but also able to work independently to meet deadlines	E	
Ability to work on own initiative	E	
Ability to prioritise a heavy workload	E	
Physical Skills		
Advanced keyboard skills.	E	
Physical Effort		
Ability to lift/carry case notes and move them across the hospital site by use of a notes trolley	E	
OTHER REQUIREMENTS		
The post holder must demonstrate a positive commitment to uphold diversity and equality policies approved by the Trust.	E	
Ability to travel to other locations as required.	E	

WORKING CONDITIONS/HAZARDS		FREQUENCY (Rare/ Occasional/ Moderate/ Frequent) R	O	M	F
Hazards/ Risks requiring Immunisation Screening					
Laboratory specimens	N				
Contact with patients	N				
Exposure Prone Procedures	N				
Blood/body fluids	N				
Laboratory specimens	N				
Hazard/Risks requiring Respiratory Health Surveillance					
Solvents (e.g. toluene, xylene, white spirit, acetone, formaldehyde and ethyl acetate)	N				
Respiratory sensitisers (e.g isocyanates)	N				
Chlorine based cleaning solutions (e.g. Chlorclean, Actichlor, Tristel)	N				
Animals	N				
Cytotoxic drugs	N				
Risks requiring Other Health Surveillance					
Radiation (>6mSv)	N				
Laser (Class 3R, 3B, 4)	N				
Dusty environment (>4mg/m3)	N				
Noise (over 80dBA)	N				
Hand held vibration tools (=>2.5 m/s2)	N				
Other General Hazards/ Risks					
VDU use (> 1 hour daily)	Y				
Heavy manual handling (>10kg)	Y				
Driving	Y				
Food handling	N				
Night working	N				
Electrical work	N				
Physical Effort	Y				
Mental Effort	Y				
Emotional Effort	Y				
Working in isolation	N				
Challenging behaviour	Y				