

JOB DESCRIPTION

POST	DATA MANAGER
ACCOUNTABLE TO	CLINICAL RESEARCH NURSE TEAM LEADERS
REPORTS TO	CLINICAL RESEARCH NURSE TEAM LEADERS
ACCOUNTABLE FOR	
<i>AGENDA FOR CHANGE BAND</i>	<i>BAND 4</i>

Job Summary:

The main purpose of the role is to support the clinical research team with all aspects of clinical trials administration, according to Good Clinical Practice (GCP), standard operating procedures (SOPs) and Trust policies.

The post-holder will be responsible for supporting the delivery of clinical trials from feasibility to archiving including (but not limited to):

- 1) Assist with the efficient and timely set up of clinical trials
- 2) Manage own workload for daily trial activity including case report form completion and amendment processing to meet internal and external deadlines.

- 3) Assist with quality assurance of all trial related documentation in accordance with relevant legislation and guidelines.
 - 4) Assist with preparation for audit and inspections within assigned teams.
 - 5) General trial-related communication in accordance with the Data Protection Act.
 - 6) Assist with maintenance of clinical trial documentation.
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- 7) Completion of Case Report Forms (CRFs) ensuring all patient data is collected accurately.
 - 8) Responsible for reporting of any Serious Adverse Events (SAE) within required timeframe
 - 9) Assist with the tracking and raising of invoices.
 - 10) Direct contact with patients and families to support study visits.

Key Relationships

Clinical leads for research
Research Nurses
Research and Development Team
Research Management Team
Principal Investigators
Lead clinicians

Main duties and Responsibilities

- Act as a point of contact for the core Research and Development team, study sponsors, clinical research organisations and specific research teams, communicating directly with them regarding data queries, monitoring visits and other enquiries relevant to trial set up and general trial conduct.
- Set up and initiation of allocated trials within an assigned team, under the guidance of the Clinical Research Nurse Team Leader.
- Maintain investigator site files and essential documentation in accordance with ICH-GCP and Trust SOPs to ensure they are kept inspection ready at all times.
- Provide administrative support to the Clinical Research Nurses and Principal Investigators for safety reporting in accordance with protocol requirements.

- Ensure collection of clinical case notes for all patients for monitoring and audit purposes, arranging and securing access to electronic records for external monitoring visits.
- Study specific training for use of electronic databases/portals
- Completion of CRFs, data entry and data query resolution in a timely manner.
- Assist with preparation for audit and inspections.
- Attend and contribute to team and departmental meetings.
- Assist with trial document archiving by following the Trust's archiving guidelines.
- Ensure that office/ trial related supplies are adequate and assist with the ordering process.
- Undertake general administrative tasks as delegated by the Team Leader.

Communication

- Communicate on a regular basis with clinical staff, senior managers, nursing and support service staff such as pharmacy, radiology and laboratory.
- Liaises with external sponsors of trials
- Requires ability to cascade clear, concise information in a timely manner
- The post holder is expected to use initiative and be able to work independently without close supervision. They are also expected to plan and organise their own time and workload activity with prioritisation, referring to the Clinical Research Nurse Team Leader as necessary.
- Working closely with research nurses within an assigned team.
- Minute taking and dissemination amongst the team.

Analytical skills

- Analyse and extract relevant data to assist in completion of CRFs

Planning and organising skills

- A high degree of organisational skills required to ensure that correct procedures are followed as per protocol
- High degree of organisational skills required to set up and maintain good record keeping/investigator site file maintenance

Physical skills

- Long periods of time spent using keyboard to input information and use of VDU for electronic communication.
- Prolonged concentration is regularly required (e.g. when checking through trial documentation and entering data into spreadsheets).
- Occasional exposure to distressing circumstances when communicating with children and families

Education and Training

- Maintain professional development whilst evaluating own knowledge with assistance from the team leader.
- Participate in departmental education programmes and study days, as appropriate.
- Support with induction, for new post holders under the direction of the Clinical Research Nurse Team Leader.

Research and Development

- As a member of the multi-disciplinary team there will be involvement in the entire process of supporting clinical trials and other research studies. This will include ensuring that all approvals have been obtained and the monitoring of progress.

Other

- To understand and adhere to local Trust policies and procedures
- To comply with mandatory training requirements.

Our values:



We pride ourselves on the quality of our care, going the extra mile to make Alder hey a safe and special place for children and their families.



We are committed to continually improving for the benefit of our patients.



We are open and honest and engage everyone we meet with a smile.



We show that we value every individual for who they are and their contribution.



We work across the Alder Hey community in teams that are built on friendship, dedication, care and reassurance.

Values Based Behaviour's

Respect:	We show that we value every individual for who they are and their contribution
Excellence	We pride ourselves on the quality of our care, going the extra mile to make Alder Hey a safe and special place for children and their families
Innovation	We are committed to continually improving for the benefit of our patients
Together :	We work across the Alder Hey community in teams that are built on friendship, dedication, care and reassurance
Openness:	We are open and honest and engage everyone we meet with a smile

PERSON SPECIFICATION

Job Title

AFC Band

	ESSENTIAL	DESIRABLE
1. Education and Training	Education to a minimum of GCSE standard or equivalent	ECDL qualification Relevant training courses in clinical research
2. Experience of...	Previous research/data collection or clinical audit experience	Experience of working within a health care system. Able to assess and interpret clinical/non-clinical information.
3. Knowledge of	Knowledge of the clinical trials process. Familiar with GCP guidelines/EU directives	Knowledge of issues relevant to paediatric research. Knowledge of patient information systems.
4. Skills	Good organisational skills Good verbal and written communication skills. Good time management.	Experience of working with MS Office applications Ability to troubleshoot effectively.

	Ability to work autonomously and as part of a team Good interpersonal skills Good attention to detail	
5. Personal Attributes	Ability to work to tight and/or unexpected deadlines. Flexible. Conscientious and hardworking.	

Mandatory Statements

1. As an organisation which uses the Disclosure and Barring Service (DBS) Disclosure service, the Trust complies fully with the DBS Code of Practice and undertakes not to discriminate unfairly against any subject of a Disclosure on the basis of conviction or other information revealed. The Trust meets the requirements in respect of exempted questions under the Rehabilitation of Offenders Act 1974, All job applicants will be subject to a criminal record check from the Disclosure and Barring Service before an appointment is confirmed. This will include details of convictions cautions and reprimands, as well as 'spent' and 'unspent' convictions. A criminal record will not necessarily be a bar to obtaining a position. A decision will be made depending on the nature of the position and the circumstances and background of the offences.
2. The Trust is pro-diversity and anti-discrimination, and takes a zero tolerance approach to racism, discrimination, victimisation, bullying or harassment. The Trust is committed to treating people equally, whether they are patients, colleagues, suppliers or other customers. We expect all of our families and staff to feel valued and respected.
3. The Trust is committed to promoting an environment that embraces diversity and promotes equality of opportunity. Staff are expected to apply the values of respect, excellence, innovation, togetherness and openness in all that they do.
4. In the course of your duties you may acquire or have access to confidential information which must not be disclosed to any other person unless in the pursuit of your duties or with specific permission given on behalf of the Trust. You must ensure that you handle personal information in accordance with the requirements of the General Data Protection Regulation (GDPR) and the Data Protection Act 2018
5. You are reminded that, in accordance with the Health & Safety at Work Act 1974, and subsequent legislation, you have a duty to take reasonable care to avoid injury to yourself and to others by your work activities, and are required to co-operate with the Trust in meeting statutory requirements.
6. You must ensure that you adhere to the Trust Infection Control policies and procedures at all times. You have a duty of care under the Health Care Act to prevent the spread of infection.
7. Within the NHS, good patient care is reliant on the availability of complete, accurate, relevant and timely data. The quality of information can limit the capability to make operational decisions about the way care is planned, managed and undertaken. Poor information quality can lead to poor decision making and may put service users at risk. High quality information means better, safer patient care. Where you are required to record data on systems, whether patient or staff data, or paper or electronic format you must ensure that it is up to date, accurate, complete and timely. You have a responsibility to

My Alder Hey. My Values.

ensure that you feel sufficiently knowledgeable about the system you are asked to use and what is required of you in order to fulfil your task accurately. Where an error is created or discovered by yourself on any system which you cannot rectify, you must contact the relevant helpdesk / system owner or your Line Manager. Please read the Data Quality and Information Governance Policies located on the Intranet and ensure you understand your responsibilities.

8. Alder Hey Children's NHS Foundation Trust is committed to safeguarding and promoting the welfare of children and young people and expects all staff and volunteers to share this commitment. Staff have a responsibility to ensure they are aware of specific duties relating to their role and should familiarise themselves with the Trust's safeguarding and child protection procedures; regular safeguarding and child protection training updates are mandatory for all staff.
9. All individuals will have some risk management responsibilities with which you are required to comply, for details of your responsibilities please refer to the current Risk Management Strategy which is available on the intranet and in the local strategies folder.
10. You must comply with all Trust policies and procedures and attend all necessary mandatory training.
11. As an employee of the Trust you will be accountable for the data entered into records and systems. It is very important that the Trust records the most up to date patient demographic details, including full name, D.O.B., address, contact number, NHS number, GP and GP Practice. This is not only to fulfil our legal obligation under Data Protection legislation, but it is also crucial in ensuring patient safety. All staff should take ownership of records that are accessed and take the opportunity to check that the data held is correct.
12. This document provides an outline of the main responsibilities of the post. It is not intended to be an exhaustive list of duties.
13. Your job description will be subject to regular review with your Line Manager.