

JOB DESCRIPTION

Job Title:	Data Management Assistant
Band	2
Care Group	Specialities Care Group
Directorate:	Clinical Support 2 Directorate
Department:	Research & Development
Location:	Royal Bournemouth Hospital – Clinical Trials Office
Accountable to:	Data Team Leader / Project Coordinator
Accountable for:	N/A
Main Purpose	The purpose of conducting clinical research is to test that a new drug, product, device or process is safe and effective. The collection of information relating to the conduct of the trial and response of the patient is vital to the accuracy of the results. Clinical trial data refers to the patient records, the assessments, test results, use of the product under review and any comparator and in some cases quality of life of the patient.

General Duties

Each trial will have developed a system for collecting the data required for collation and analysis of the results, these are called Case Report Forms (CRFs) and may take the form of paper forms or web based databases. The Data Management Assistant is integral to assuring the source data, found in the patient's clinical records is complete and accurate and that the trial management files are kept tidy, up to date and accessible.

Communication and Working Relationship Skills

Provide support for the Clinical Trials Nurses and Project Coordinators by:

- Assisting the research nurses and project co-ordinators in collating trials data and enter this onto the appropriate case report forms, as required by the sponsors and Investigator and in compliance with ICH Good Clinical Research Practice guidelines.
- Liaise with Clinical Research Associates and Study Monitors and assist them during monitoring visits.
- Complete the forms for and report Serious Adverse Events within 24hours of the research team being aware of the event. This includes discussing the case with clinicians, including nurses and Consultant Medical staff

- Organise regular, convenient review time with research nurses and Principle Investigators (PI's) to assess data accuracy and clinical trial protocol adherence.
- Maintain a good relationship with other members of the multidisciplinary team and other health care agencies. Promote and maintain good communications with all members of the multidisciplinary team.

Analytical and Judgemental Skills

- Assist in the collection and collation of data and statistics as required for audit, clinical governance and in-house research.
- Have in depth knowledge of the clinical trials protocols and check the patient's records to ensure protocol adherence. Notifying the research nurses and/or PI's if any missing data is noted.

Planning and Organisational Skills

- Assist in the collection and collation of data and statistics as required for audit, clinical governance and in-house research.
- Obtain copies of reports, x-rays and Scans as required for clinical trials and audit.
- Assist in organising and monitoring the follow up of patients who have completed treatment within a clinical trial.
- Assist the research nurses and project coordinators in collecting the evidence for submission to the research and development office.
- To develop own managerial skills by organising own work load and ensuring databases and case report forms are current.

Responsibility for Patient/Client Care, Treatment and Therapy

- Monitor the patient's clinical records to confirm all assessments and treatments are performed
- Respect the confidentiality of patients and staff at all times.

Responsibility for Policy / Service Development

- Contribute to team meetings and reviews with ideas for service and efficiency improvements.
- Work with the data team and research nurses to develop and maintain efficient, user friendly trackers.
- Contribute new ideas and participate in further study and research
- .Participate with senior staff to initiate specific projects in the department.

Responsibility for Finance, Equipment and Other Resources

- Be responsible for the care and security of equipment, promptly report faults or breakages, identifying dangerous equipment and removing this to a place of safety as per Trust policy.
- Maintain stocks of stores required to effectively maintain the Clinical Trials Office.

Responsibility for Human Resources, e.g. Supervision, Training, HR Advice and Management

- Assist in the orientation and training of new staff.
- Be familiar with Trust Personnel Policies including:
 - a) Health and Safety
 - b) Disciplinary
 - c) Grievance
 - d) Staff / Patient accidents
 - e) Complaints

Responsibility for Information Resources and Administrative Duties

- Provide general clerical and office management duties to the research team including dealing with telephone queries.
- Organise patients electronic records to provide a chronological flow of source data to assist monitoring and inspections.
- Assist in the maintenance of the Investigator study files, keeping these tidy and updated by appropriate filing of documentation.
- Provide a high standard of data collection and entry, this may include working within a variety of web-based platforms.
- Liaise with senior staff at any time if any problems arise affecting the integrity of the databases.

Responsibility for Research and Development

- Work independently within clinical trials protocols
- Keep an up to date research curriculum vitae for presentation to the sponsors and managers of clinical trials.

Freedom to Act

- Work within the Standard Operating Procedures for research, Good Clinical Research Practice and Clinical trial Protocols.

- As part of this role, work will be regularly monitored by internal and external clinical trials monitor, the accuracy of data entered in the Case Report Form is the responsibility of the post holder.

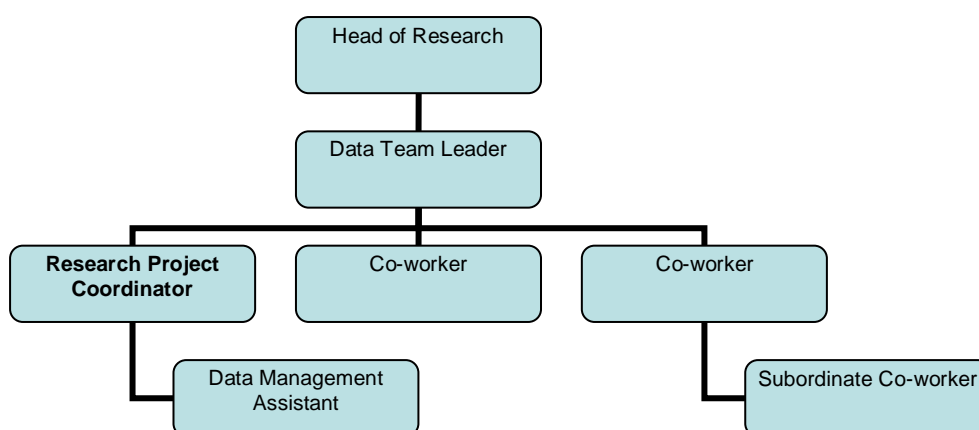
Mental, Physical, and Emotional Effort

- This post involves long periods of sitting with occasional light physical effort required in moving portable equipment and stores, lifting and moving aids are available.
- This post requires long periods of intense concentration, often computer based.
- The post holder will be reading clinical records which may occasionally be distressing.

Any Other Specific Tasks Required

- Archiving documentation of closed trials.

Organisational Structure of Department



Transforming our Hospital Services in Dorset

This is a very exciting time to join our hospitals in Dorset. We are in line to receive a significant national investment of £201 million to help transform our services and redevelop Poole Hospital and the Royal Bournemouth and Christchurch Hospitals, now merged as University Hospitals Dorset. We have been able to access these national funds because we have such a good plan in Dorset.

Our vision is to join up our services so they can be delivered in a more integrated way. We have a great opportunity together to improve outcomes for patients, make better use of all our resources, and ensure our services can be provided on a sustainable basis.

For developing our workforce, the aim is to establish modern, well-equipped centres of excellence with sustainable roles for staff, standardisation of education and training so that we can attract and retain skilled clinical and non-clinical staff to Dorset. This is a great opportunity for you to be part of the transformation change activity taking place following the merger of two hospital trusts to form University Hospitals Dorset NHS Foundation Trust last October.

Partnership with Bournemouth University

We are proud to be affiliated with Bournemouth University, and working closely in partnership with them, this provides us with the opportunity for establishing joint posts, shared learning and training, sharing facilities, and joint project work.

CONDITIONS OF SERVICE

As laid down by the University Hospitals Dorset NHS Foundation Trust.

Smoking

The Trust has a responsibility to provide a safe and healthy environment for everyone who is working, visiting or living on hospital premises. Smoking is NOT allowed on site except for within the designated smoking areas and shelters for staff and patients.

The Trust will not tolerate smoking in undesignated areas and there is a zero tolerance approach to all staff who continue to do so. We will continue to provide support to staff, patients and visitors who want to give up smoking.

In the interests of promoting responsible healthcare all staff should refrain from smoking when off-site in uniform or wearing an identifying NHS badge in any public place.

Data Protection

All staff are required to comply with the Data Protection Act and the Trust's Data Protection Policy. Staff are responsible for ensuring that any personal data which they hold is kept securely; that personal information is not disclosed either orally or in writing to any unauthorised third party; that personal data is only accessed where there is a legitimate business need and only where such processing is consistent with the purposes for which the data was collected.

Equality and Diversity

The Trust is positively committed to the promotion and management of diversity and equality of opportunity. Equality and diversity is related to the actions and responsibilities of everyone – users of services including patients, clients and carers; work colleagues; employees; people in other organisations; the public in general.

All employees have a responsibility to ensure that they act in ways that support equality and value diversity and must comply with the responsibilities placed upon them by employment legislation and the equality duties.

Health and Safety at Work

Everybody within the Trust has a legal responsibility for the health, safety and welfare of themselves and others at work. These duties are set out within the Health and Safety at Work etc. Act (HASAWA) 1974, the Management of Health and Safety at Work Regulations (MHSWR) 1999, and in other relevant regulations and guidance notes.

All Staff

In accordance with HASAWA and the Trust Health & Safety policy, all staff have legal responsibilities;

- to take reasonable care for themselves and others that may be affected by their acts/ omissions
- to co-operate with their manager/ supervisor to enable them to carry out their legal duties e.g.
 - shall report all hazards and defects to their line manager/ supervisor
 - shall report all accidents, incidents, near-miss events to their manager/ supervisor and via an adverse incident report (AIR) form (Trust policy)
- to use all work equipment, materials and substances in accordance with any training and instruction provided (e.g. medical devices, chemicals, mechanical aids, machinery, plants, vehicles, and personal protective equipment)
- to ensure they attend all annual mandatory training and attend health and safety training as required for the post.
- to comply with trust and department health, safety & risk policies and procedures
- not to interfere with or misuse anything provided to secure health and safety .e.g. wedge fire doors open, remove first aid equipment, break locks off systems

All Managers/ Heads of Department and Clinical Leaders

In accordance with the Trust's Risk Assessment policy and Risk management strategy, all managers/heads of department and Clinical Leaders are responsible for ensuring that they and their staff, comply with all Trust and department health and safety policies and procedures.

Safeguarding

The University Hospitals Dorset NHS Foundation Trust is fully committed to safeguarding the welfare of all children and young people, and vulnerable adults by taking all reasonable steps to protect them from harm. All staff will receive appropriate training and induction so that they understand their roles and responsibilities and are confident about carrying them out.

Infection prevention and control

The prevention and appropriate management of infection is of paramount importance in the quality and safety of the care of patients, and to the safety of visitors and members of staff. It is the responsibility of all staff to be aware of, assess and minimise these risks and comply fully with Infection Prevention and Control Policies.

The Health Act 2008 establishes a Code of Practice for the Prevention and Control of Health Care Associated Infections. It sets out criteria by which NHS managers ensure that patients are cared for in a clean environment, with a safe water supply, where the risk of Healthcare Associated Infections (HCAI) is kept as low as possible.

Managers, Heads of departments and Clinical Leaders are responsible for ensuring that:

- The necessary equipment and mechanisms are in place to support infection prevention
- health care workers are free of and are protected from exposure to communicable infections during the course of their work, and that all staff are suitably educated in the prevention and control of HCAI

Carbon sustainability

The Trust is committed to continual improvement in minimising the impact of its activities on the environment and expects all members of staff to play their part in achieving this goal and in particular to work towards a 28% reduction in carbon emissions by the end of 2020/21 (based on a 2013 baseline).

DBS/Disclosure and Barring Service (CRB)

As part of our recruitment procedure this post will be subject to a Criminal Record Disclosure. A Disclosure is a document containing information held by the police and government departments. Disclosures provide details of a person's criminal record including convictions, cautions, reprimands and warnings held on the Police National Computer. Where the position involves working with children, Disclosures will also contain details from lists held by the Department of Health and Social Care and the Department for Education and Skills (DfE) of those considered unsuitable for this type of work.

This post is subject to the policies, procedures and rules approved by the Trust and as varied from time to time. All staff are required to familiarise themselves with, and comply with the Trust's policies, procedures, rules or statements of practice. These can be accessed through the Intranet, your Department Manager, or through Human Resources.

Job Description Agreement

All job descriptions which are developed for job matching purposes must be signed by both the line manager and the staff member and the effective date of when the role changed entered. Please see re-grading and job evaluation policy.

Any job descriptions amended or updated through the results of a personal review should also be signed and dated by both the line manager and staff member and a copy retained on the personal file.

Signed..... Date.....Manager

Signed.....Date.....Employee

Review of this Job Description

This job description is intended as an outline indicator of general areas of activity and will be amended in the light of changing service needs. This job description will be reviewed in conjunction with the post holder on an annual basis at appraisal.