

South East Scotland Cancer Research Network

JOB DESCRIPTION

1. JOB IDENTIFICATION

Job Title: Clinical Trials Data Manager

Responsible to: Senior Research Data Manager

Department(s): South-East Scottish Cancer Research Network

Directorate: Cancer Services

Operating Division: NHS Lothian

Job Reference: 220134

No of Job Holders: 17.6 WTE

Last Update (insert date): 20/06/2025

2. JOB PURPOSE

To provide data management support for cancer clinical trials, undertaken within the Edinburgh Cancer Centre. This may include trials from early phase to large multi-centre phase 3 and 4 trials.

The role includes regulatory submissions, extracting data from patient records into both electronic and paper case report forms (CRFs) and liaising with pharmaceutical companies, clinical research organisations, study sponsors and co-ordinating centres to ensure the safe, efficient and professional operation of the clinical trials portfolio within the department.

To record all patients and their activity on the EDGE database including finance and visit activity in a timely manner ensuring the patient status is up to date.

To provide reports of clinical trial activity within team(s) regarding current and proposed trial portfolio.

3. DIMENSIONS

The Edinburgh Cancer Centre is part of the South-East Scottish Cancer Research Network (SESCRN) which encompasses several partners involved in the delivery of cancer clinical trials to patients across the south east of Scotland, including:

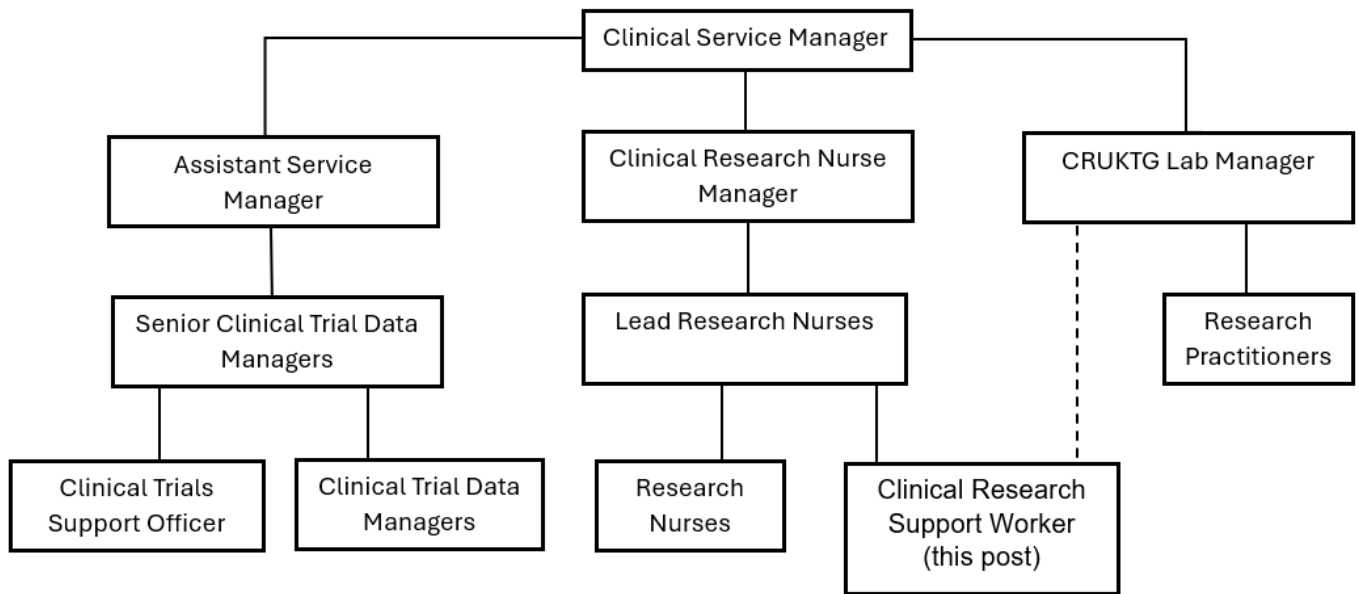
- 4 NHS Boards and 8 hospital sites across NHS Lothian, NHS Borders, NHS Fife and NHS Dumfries & Galloway
- Cancer Research UK
- Experimental Cancer Medicine Centre

The Edinburgh Cancer Centre also hosts a Cancer Research UK Centre with the specialist services to deliver early phase clinical trials

- Approx 9,000 newly diagnosed cancer patients per year across the SESCRN region.
- Approx 1,000 new patients consented into cancer clinical trials per year in SESCRN region.
- Around 150 'active' clinical trials registered on SESCRN's EDGE database providing trials for all tumour types.
- Approx 60 clinicians, 30 nurses and 21 data managers actively involved in clinical trials across the region.
- SESCRN is divided into 8 teams, each with a clinical lead and these teams provide support for clinical trials in different tumour types as outlined below:

Team	Tumour Groupings
1	Early Phase, Melanoma, Colorectal, Upper GI & Hepatobiliary
2	Breast, Gynaecology & Sarcoma
3	Lung, Head & Neck, Brain
4	Urology & Palliative Care
5	Radiotherapy
H	Haematology
RHSC	Sick Children
BS	Breast Surgery

4. ORGANISATIONAL POSITION



5. ROLE OF DEPARTMENT

- To develop and maintain a portfolio of high quality, peer-reviewed clinical trials and studies across all tumour types to maximise the treatment options offered to patients.
- To increase the number of patients entering clinical trials and improve patient awareness of trials.
- To improve access to trials for all patients within the Edinburgh Cancer Centre and local cancer centres across the Network.
- To ensure that all trials are conducted in accordance with the International Conference on Harmonisation Good Clinical Practice Guidelines for the Conduct of Clinical Trials (ICH GCP), European Union Directive on Clinical Trials, Research Governance Framework, Ethics Committee regulations and other specific guidelines and operating procedures.
- To ensure that staff working in clinical trials have access to appropriate training and continuing education.

6. KEY RESULT AREAS

- To assist in ensuring that protocol required activities are done according to protocol and in compliance with ICH GCP.

- Prepare trial specific documentation for the accurate collection of clinical data as directed by protocol and ensure accurate, timely reporting of collected data per individual trial and sponsor requirements.
- To ensure timely submission of accurate and complete CRFs and reporting of Serious Adverse Events (SAEs) to trial sponsors.
- To organise and prepare trial documentation for visits by trial monitors and clinical research associates and to act as the main contact for monitors/sponsors for all data related issues.
- To lead on the preparation and submission to Research & Development (R&D) for management approval of trials, liaising with various hospital departments such as Pharmacy, Laboratory Medicine and Radiology to seek their support and approval of every trial.
- Responsible for ensuring that trial documents are current (by version control) and disseminated to the medical and nursing staff within the research team.
- To attend research team meetings, preparing and presenting regular updates on specific trials as required.
- To take responsibility for the data management and coordination of specific trials across all cancer groups as required to meet departmental demands.
- To continue to update skills and education for specific trials by attending and participating in local and national meetings as required.
- To maintain accurate data on relevant trials on the EDGE database and assist in the preparation of reports as requested by the Research Network Manager or senior network staff.
- To assist the Research Network Manager and other senior network staff in the collation of accrual figures for patients into trials across the region as required for Scottish Government monitoring reports.
- To liaise with the R&D Departments finance staff in relation to patient recruitment figures to facilitate the reclaiming of patient payments from commercial and/or non-commercial research funding bodies.
- To attend and participate in SESCO forums and working groups (e.g. participation in the Standard Operating Procedure group)
- To participate in the preparation for potential audits and/or inspections of the Network by research governing and regulatory bodies such as the Medicine and Healthcare Regulatory Agency (MHRA).
- To offer additional administrative assistance as needed to ensure the smooth operation of clinical trials

7a. EQUIPMENT AND MACHINERY

Personal Computer / Laptop / VDU

Keyboard

Printer
Photocopier/Scanner
Telephone
Video Conferencing Equipment

7b. SYSTEMS

- Computer systems:
 - TRAK: access patient administration system to view patient demographics, relevant correspondence and view results of investigations.
 - APEX: access laboratory system to track patients' test results.
 - EDGE trials database: updating and maintaining information on current & new trials.
 - Completion of electronic Case Report Forms (CRFs) where applicable.
- Adhere to the systems established via the SESCO Standard Operating Procedures for the conduct and delivery of clinical trials.
- Adhere to the manual and electronic systems on submitting trial applications to R&D Departments for approval.
- Maintain trial section of patients' medical records.
- Maintain manual and electronic case report forms for each patient entered into a trial in accordance with the guidelines set out in the trial protocol and in the SESCO SOPs.
- Adhere to Medical Records Dept tracking system when using patients' medical notes.

Note: New systems may be introduced (and removed) as the organisation and technology develops, however training will be provided.

8. ASSIGNMENT AND REVIEW OF WORK

The post-holder is line managed and receives support and guidance from the Senior Data Manager. The post-holder is expected to work autonomously and manage their workload on a daily basis, assessing and prioritising the data management and administrative needs of the trials portfolio on an ongoing basis.

Appraisal, objective setting and personal development plans are agreed jointly with the line manager on an annual basis and reviewed at regular periods.

9. DECISIONS AND JUDGEMENTS

The post holder is responsible for planning the order of work based on the current and future trials portfolio of the team(s) and is expected to use initiative, logic and discretion when making decisions about work prioritisation and identifying solutions to problems.

A high level of discretion, sensitivity and maturity is expected when dealing with confidential patient information.

10. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB

Balancing the daily priorities of each trial to ensure that all patients are treated and reviewed according to the trial schedules, as well as the demands of the trial coordinating centres to monitor all trial documentation on site within tight timescales.

Balancing the workload across several tumour sites and research teams within the Edinburgh Cancer Centre while ensuring that data capture for all trials in the team's portfolio is kept up-to-date.

11. COMMUNICATIONS AND RELATIONSHIPS

The jobholder communicates with:

Internal:

- SESCO Manager, Research Nurses, Assistant Service Manager, Data Managers, Administrator, junior and senior medical staff within the Network.
- Negotiation with various levels of professional staff in hospitals departments, e.g. Pharmacy, Laboratory Medicine, Radiology, Medical Records.

External:

- Management, Finance and Administrative Staff in R&D Departments in NHS Lothian, NHS Fife, NHS Borders and NHS Dumfries & Galloway in relation to obtaining management approval and tracking payments for trials.
- Nursing and Health Records staff in local Cancer Units across South East Scotland in relation to accessing patient treatment data for the purposes of trial data collection locally.
- Representatives from pharmaceutical companies, Clinical Research Organisations and Trial Coordinating Centres with regards to documentation, queries, monitoring etc.

12. PHYSICAL, MENTAL, EMOTIONAL AND ENVIRONMENTAL DEMANDS OF THE JOB

- Physical: Moderate physical effort for prolonged periods, mostly sitting at desk using laptop/PC. Need to be fairly fit to transport patient case notes across hospital site.
- Mental: Concentration required when inputting data to database accurately; work pattern is unpredictable and is subject to frequent interruption, in terms of prioritising workload to meet the demands of a large volume of clinical trials.
- Emotional: exposure to distressing or emotional circumstances on occasion when accessing patient records or dealing with upset patients and carers on the telephone, and interaction with research nurses involved in treating cancer patients. Occasionally exposed to conflict when negotiating with senior staff over trial-related issues.

Environmental: The post may require occasional travel to other hospitals sites across the Network (ie:

Fife, West Lothian, Borders and Dumfries). Occasional travel to national cancer trial 'start-up' meetings required.

13. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB

- Educated to degree level or equivalent experience.
- Previous NHS experience is preferable.
- Experience in an academic or commercial research environment involving data management of clinical trials is desirable.
- Knowledge of ICH GCP, the European Union Directive on the Conduct of Clinical Trials, procedures for the submission of trials to NHS R&D Departments and awareness of the Research Governance Framework for the NHS in Scotland.
- Knowledge of medical terminology and basic anatomy desirable.
- Strong inter-personal skills and ability to interact with various levels of NHS staff, in particular senior clinicians and research nurses.
- Excellent verbal and written communication skills.
- Competent in the use of computers and knowledge of Microsoft software programmes, internet, email.
- Excellent organisational skills with the ability to pay attention to detail and work independently.
- Ability to learn quickly and to interpret information and instructions accurately.

14. JOB DESCRIPTION AGREEMENT

A separate job description will need to be signed off by each jobholder to whom the job description applies.

Job Holder's Signature:

Date:

Head of Department Signature:

Date: