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| 1. **JOB IDENTIFICATION** |
| **Job Title:** Clinical Research Co-ordinator (CRC)  **Responsible to:** Senior Research Nurse  **Reports to:** Research Nurse Manager  **Directorate: Regional Services**  **Department(s):** Beatson CRF Network sites within Greater Glasgow and Clyde  Health Board |
| **2. JOB PURPOSE** |
| To coordinate and manage a portfolio of phase II-III Clinical Trials in oncology and haematology, working in accordance with ICH GCP (Good Clinical Practice) and the EU Directive, providing efficient data management for all studies run through Royal Alexandra Hospital, Inverclyde Royal Hospital and New Victoria Hospital, part of The NHS Research Scotland , Cancer Research Network (NRS CRN) |
| **3. ROLE OF DEPARTMENT** |
| The NRS CRN is an initiative supported by the Chief Scientist Office of the Scottish Government to increase, support and sustain clinical trial activity in cancer care in partnership with the UK Clinical Research Collaboration (UKCRN). Initial targets for the NRS included increasing the overall recruitment of cancer patients to clinical trials. This has been achieved by improving the supportive research infrastructure in Cancer Services in Scotland.  The hub of NRS CRN – West of Scotland is the Beatson West of Scotland Cancer Centre (BWoSCC). From here extends the network of clinical trials staff based in hospitals in each of the West of Scotland Cancer Network NHS Health Board areas – NHS Greater Glasgow and Clyde, NHS Ayrshire and Arran, NHS Forth Valley and NHS Lanarkshire.  NRS Cancer - West research staff include research nurses and trial practitioners, clinical trial radiographers, clinical trial coordinators, Clinical Research Coordinators and regulatory administrators. Outside the BWoSCC, research teams support local recruitment to cancer clinical trials to allow patients with cancer the opportunity to participate in research at hospitals nearer to home.  The portfolio of clinical research offered across the West of Scotland includes trials of new drug treatments as well as studies that aim to improve the patient journey and experience. Research also considers the genetics, prevention, and diagnosis of cancer.  Trials that assess new types of radiotherapy are also a vital research area and NRS Cancer - West Clinical Trial Radiographers provide leadership in all aspects of radiotherapy trials across the West of Scotland region. |
| **4. ORGANISATIONAL POSITION** |
| **4. ORGANISATIONAL POSITION**    Lead Research Nurse for  Cancer Clinical Research  Research Nurse Manager team Late Phase Team  Research Nurse Manager ATiMPs &BMT  ATiMPs & BMT  Research Nurse Manager Earlyphase &haem-onc team  eARLY  Early phase &haem-onc team  Clyde & NVH research staff  Beatson WoSCC Research Staff  research staff  QEUH Research Staff  research staff  Beatson WoSCC Research Staff  research staff  Senior RN RN  Band 5 RN  Senior RN CRC  bAND    Band 5 RN  SeniorRN  RN  Band 5 RN  Senior RN  RN  Health Care Support Assistant(s) and Administrative staff based within new Research Unit (B6)  new Research Unit (B6) |
| **5. SCOPE AND RANGE** |
| A Clinical Research Coordinator (CRC) supports a portfolio of trials, approximately 15 trials depending on the size and nature of the trials, in addition to the follow up of closed to recruitment studies.  A range of cancer disease sites including haematology may be covered in this portfolio.  The number of patients participating in each trial varies depending on the epidemiology of the cancer site and the trial patient eligibility requirements.  For each patient on trial the CRC works with the clinical team to ensure assessments are carried out, samples are taken and data is available for the completion of case report forms. Following initial treatment, each patient will often require follow-up for 5 years, until progressive disease or until death. This is dictated by the study specific protocol.  The NRS CRN -W has a set of SOPs (Standard Operating Procedures) which each CRC works to, ensuring uniformity of practice within the Network and ensuring adherence to the ICH GCP Guidelines and the EU Directive on Clinical Trials. The EU Directive came into force on 1st May 2004 and is a legal requirement for participation in Clinical Trials. |
| **6. MAIN DUTIES/RESPONSIBILITIES** |
| Providing co-ordination and data management to clinical trials that are run through the NRS-W. This involves but is not limited to:   * Maintaining the Investigator Site file (ISF) on behalf of the Lead Clinician (Principal Investigator-PI). The ISF is a recognised data set and is part of Good Clinical Practice Guidelines (GCP) * Checking patients are eligible for a clinical trial by reviewing the inclusion and exclusion criteria of the study in conjunction with the patient’s clinician * Randomising/registering patients for treatment and relaying the treatment allocation to the responsible clinician, the clinical team and pharmacy * Ensuring investigations (e.g. blood tests, CT-scans, Quality of Life Questionnaires) are carried out as per the study protocols. This involves working closely with the Clinical Trials Nurse and close liaison with various members of the hospital staff from a wide range of departments * Preparation of a study schedule data collection forms for clinicians to use at clinic indicating the study procedures required at each specific patient visit * Review/extract data from e-health systems and other patient notes onto case report forms (CRFs) for patients on study and in follow-up, ensuring the data is accurate and up to date. The CRC must discuss the study specific data collection with the clinician to ensure that information is documented to verify source data. This includes documenting patient’s previous medical history, physical examinations, laboratory results, medications taken throughout treatment with appropriate start and stop dates, adverse events occurring throughout the study (again with appropriate start and stop dates) * Requesting and sending pathology samples or CT scan reports for independent review. Maintaining accurate records of these activities * Some studies are translational studies only. This is where patients are consented to provide blood and/or tumour samples. In this setting, the CRC is responsible for the labelling, packaging and arranging courier/postage of these samples. The transfer of biological material is strictly regulated, and appropriate regulations must be adhered to * The CRC will contact other hospitals to request any information regarding treatment at that site (for example, information on original diagnosis or surgery or unexpected hospital admission * Reporting all Serious Adverse Events (SAEs) that occur in trial patients to the study sponsor, via their systems as outlined in the protocol and as per GCP * Answering any queries that may be generated from the data collected within specified timelines. If appropriate, clarification of the data must be discussed and signed by the PI responsible for the study * Assisting R&I finance teams in tracking all payments throughout each clinical trial including completion of activity logs and requesting invoices to be raised * Liaising with the coordinating centre/sponsor organisation personnel regarding the trial and updating the local study as required team * Organising site initiation visits (SIVs) for new studies, ensuring all the study personnel are in attendance (i.e. clinician, pharmacists, nurses, CRC) and all regulatory documentation is in place * Attending study specific start-up visits with the PI responsible for the study (or alone as their representative) to go through all the study procedures before the study open to recruitment and any patients have been recruited * Working regularly with external sponsor organisations, commercial and non-commercial and supporting and preparing for monitoring visits being carried out to verify all study procedures are being followed as per study specific protocol. This would involve organising a meeting room and making sure all the patient data is available and up-to-date. Feedback any issues from this meeting to the clinician to address any queries or problems that may have been identified * Passing on information to other study personnel when new information becomes available e.g., unexpected side effects which can result in the suspension of the clinical trial and require existing patients to stop study treatment * Archiving of the study documentation as per standard operating procedures (SOPs). * General office duties will include answering the telephone, photocopying, filing, scanning and any other duties necessary to help with the smooth running of the trials and office |
| **7. SYSTEMS AND EQUIPMENT** |
| EDGE™  The EDGE system is a trial management system and is used to not only to record all patients on clinical trials and progression through the trial, but is also used by multiple stakeholders for financial, reporting and safe document storage for clinical trial essential documents. The CTC will be responsible for maintaining and updating information for the patients and specific hospital site trial information.  eCRF  Case report form (CRF)  Used to collect the data required for each, individual study in a clear and precise format. This involves liaising with the patient clinician and research nurse to ensure that all the information is accurate and all the protocol investigations have been performed. Historically, these CRFs were mostly paper based, however, increasing these are via electronic system which may vary from sponsor company to company. Training will be provided on the individual systems  Safety Systems  The CTC will be required to liaise with PI and will facilitate Serious Adverse Event (SAE) reporting via the sponsor organisation’s dedicated system for this. (Occasionally this will be paper based but this is becoming increasingly rare)  SReDA  This is the national Research and Development database where the full study document set is stored following national study wide review and permissions for all regulatory authorities are in place. Local R&I department will maintain non patient information on this system  E-health systems  This includes but is not limited to Clinical Portal (patient case notes), TrakCare Live, and other system(s) necessary for role.  Informed consent forms (ICFs) require to be scanned onto Clinical Portal as this information must be included in the patient record. The CTC will undertake this duty as required.  Microsoft Office  Compile reports, format documents (such as Patient Information Sheets) by adding logos and local information, type letters and general administration.  Adobe Acrobat Reader Allows conversion of documents created in other programs into Adobe to enable sending or comment and review as a PDF file  PowerPoint - To create presentations and handout reports for review if requested  Excel Create spreadsheets which may be useful for tracking patient’s treatment, adverse events and  scheduling follow-up appointments or timelines for scans  Outlook 365  Email - main method of communication with all key study personnel and NHS Greater Glasgow and Clyde Health Board  Interactive Web Response Systems (IWRS) and Interactive Voice Response Systems(IVRS)  Telephone or on-line system used mainly in blinded studies designed to register/ randomised patients, supply  medication, allocate patient Kit numbers (these are held in pharmacy, each patient being allocated a different number for each treatment), break blinding codes (this is done in an emergency)  Chemo Care  This is the national system used for prescribing patients chemotherapy and other treatments This is used as source data to check whether the patient has received treatment or not and the details of this.  Departmental Shared Drives  Access to the appropriate shared drives and navigation and maintenance of any information as requested |
| **8. DECISIONS AND JUDGEMENTS** |
| CTCs are allocated a number of studies to work on and it is their responsibility to prioritise and manage their workload in order to work efficiently. CTCs can be responsible for 10-15 actively recruiting studies at any one time in addition to managing studies in follow up, for some older studies, this is survival data only.  Deadlines for study data return will be imposed by the sponsor organisation and contract, and CTCs must meet these deadlines whilst dealing with the day-to-day management of other studies such as queries, reporting serious adverse events and answering urgent telephone calls.    Decisions regarding time management must be applied to each working day to ensure that work is up-to date and accurate. Support will be provided by Senior Research Nurse at site  Each CTC should have highly specialised working knowledge of all their studies to be able to answer questions from clinicians, nurses and other personnel involved with patients on study treatment. It is essential that any questions regarding a study are answered quickly and accurately so that the patient’s treatment within a study progresses in a timely manner.  The individual protocol for each study includes the trial outline and objectives, inclusion/exclusion criteria, study medication and treatment plan, clinical assessments, laboratory assessments safety reporting, statistics and analytical plan, information on data monitoring committee, interim analyses adverse events, withdrawal, follow up and subject replacement policy, definition of progressive disease  CTCs will receive requests from companies for additional information regarding the study patients and other department information – good knowledge of confidentiality and data protection is essential  The PIs for studies based outside of the BWoSCC studies are not always on site, so organisation skills and communication skills are essential for optimising time with the clinician and robust systems in place for contacting them when off site. |
| **9. COMMUNICATIONS AND RELATIONSHIPS** |
| The appointee will be expected to communicate and develop good working relations with the following:  **Clinicians**  CTCs have various levels of communication with the clinicians who are involved with and participating in the studies they co-ordinate and manage. This will be the PI and any other clinicians assigned to the study and the specific patient group such as Specialist Registrars. This may range from registering a patient into a trial, to arranging a time to meet to have documents signed and ensuring data is up- to-date and accurately transcribed from the case notes. Clinicians can on occasions also request study updates for patients on studies. This would require compilation of reports detailing patient’s status within the study and in some cases, relaying this information at departmental meetings. Communication with the study clinicians requires the CTC to use their discretion as and when to make demands on the clinician’s valuable time.  **Sponsor representative- Study Manager, Clinical Research Associate and others**  For most studies, the CTC is the main point of contact and works as an intermediary between the clinician and the company representative. This involves answering queries from both parties, organising monitoring meetings/visits and informing all study personnel of any study updates. CTCs would be expected to communicate any problems or concerns our clinicians may have with the study to the company representative and to inform the relevant clinical team of the company’s procedures and expectations. To discuss with the clinician any side effects of the patients treatment to establish if this is related to the study drugs and report to the drug company if necessary. Prompting the clinician via case notes to ensure that any investigations required by the study are performed.  **Clinical Research Nurses**  Close working with the research nurse(s) is essential in maintaining day to day management of study and ensuring good communications between both parties , particularly in respect of patient safety information    **NRS Regulatory Administrator (RA)**  The RA is responsible for facilitating submission of Network hosted studies to Research and Innovation (R&I) department to ensure that local necessary approvals for the study have been granted. The CTC will liaise directly with the RA to ensure all applicable information has been collected for the submission, obtaining signatures as necessary. Other aspects of communication with the RA are for study amendments and approvals and accessing information on the national R&D database, sReDA  **Pharmacy**  There are designated Clinical Trials Pharmacists and Technicians at each research site. The CTCs liaise with them on a regular basis, advising on new trial recruits, and changes with existing patients, drug allocation following study randomisation and sharing documents that may require to be stored in ISF  **Pathology**  Regular communications with pathology secretaries and Bio-repository team in respect of archival tumour blocks release for analysis by sponsor pathology team  A wide range of other personnel such as ward staff, radiologists, haematologists and medical secretaries. To ensure that all the information required to update CRF pages such as scan reports, study drug supply, test results and letters regarding any patients on study is available. For some studies the CTC may have to organise tumour samples, copy scans or blood reports to be sent away for independent review. |
| **10. PHYSICAL DEMANDS OF THE JOB** |
| Clinical trials are not paperless. Many ISFs and CRFs are large and cumbersome to move and CTCs have to lift these from high shelves on a daily basis. Space for all these CRFs is very limited. This means that CTCs are often working in an office that has very little workspace.  Data for all closed studies is eventually archived off site. This involves shredding all non- essential documentation, condensing the CRF files weighing and lifting heavy boxes. These boxes can weigh up to 15kg.  The largest part of the working day is desk bound, using PC or laptop with multiple screens for e-mail, data entry, generating / compiling reports and typing up letters.  Physical skills – using and understanding medical terminology, accurate interpretation of patient data, advanced keyboard/computer use, excellent time management/organisational skills and working quickly and efficiently under pressure. |
| **11. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB** |
| Ensuring that you have a highly specialised working knowledge of many study protocols whilst avoiding confusion. This requires allocating time for intense concentration to ensure you have understood all the protocol procedures and requirements.  Potential for having to re-organise daily planned workload whist having to respond to urgent requests for information and dealing with interruptions to your working day.  Working under pressure to meet study deadlines as well as dealing with other queries or reporting SAEs for patients on other trials whilst ensuring the quality of the data is maintained. |
| **12. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB** |
| * Qualifications to degree level or equivalent * Good knowledge of medical terminology * ICH GCP training (provided once in post) * Clinical research experience and knowledge of current legislation in the area (eg. EU Directive for Clinical Trials) * Excellent organisational skills * Excellent communication skills (oral and written) * IT literate * Ability to work under pressure and ensure deadlines are met * Work on own initiative and as part of a team * Ability to travel to national meetings on rare occasions |
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