# **Cancer Research UK West Of Scotland Clinical Trials Unit**

## **Beatson West of Scotland Cancer Centre**

**Glasgow**

**Job Description**

|  |  |
| --- | --- |
| 1. JOB IDENTIFICATION   **Job Title:**  **Department(s):**  **Job Reference number (coded):** | Clinical Trials Assistant (CTA)  Cancer Research UK Clinical Trials Unit (CTU)  Beatson West of Scotland Cancer Centre (BWoSCC) Glasgow |
| 1. **JOB PURPOSE**   To provide full and comprehensive administrative and data management support to the CRUK CTU BWoSCC Glasgow in accordance with the current legislation (EU Clinical Trials Directive and ICH/GCP Guidelines). | |
| **3. ORGANISATIONAL POSITION**  Please refer to the current version of the Cancer Research UK Clinical Trials Glasgow Organisation Chart.  The CTA’s support the BWoSCC CTU Participatory Activity will report directly into the Head of Trial Coordination (HoTC). | |

|  |
| --- |
| **4. SCOPE AND RANGE**  The Cancer Research UK CTU Glasgow is based within the Beatson West of Scotland Cancer Centre (BWoSCC) and is one of only 7 major Cancer Research UK Trials Units within the UK. The BWoSCC is the lead centre for the delivery of non-surgical cancer care for the West of Scotland. It serves a population of 2.8m, and has clinical links with 16 hospitals in five surrounding health board areas.  The main purpose of the CTU is to advance cancer treatment and knowledge by developing trial ideas, building these into fundable projects and then setting up and coordinating these trials. There are approximately 40-50 trials that the CTU coordinates at any one time, the vast majority (over 90%) of these clinical trials of investigational medicinal products (CTIMPs), involving the administration of cytotoxic treatment (chemotherapy) and many are large scale with national and international participation. These trials are referred to as in-house trials.  As well as coordinating the in-house trials, the Unit also participates in other commercial and non-commercial trials. The Unit supports the recruitment of BWoSCC patients into these trials and subsequent follow-up and data collection of these patients. The Unit provides organisation and support for around 50 local clinical and medical oncologists, haematologists and palliative care physicians wishing to give their patients with cancer access to a clinical trial. There are approximately 160 open trials running through the department in 13 different tumour types at any one time. Some of the research carried out may be the first in human administration of a particular chemotherapy.  In collaboration with the ISD Cancer Clinical Trials Team in Edinburgh, the CR-UK CTU Glasgow is an accredited National Cancer Research Institute (NCRI) CTU. This collaboration is known as Cancer Clinical Trials Unit Scotland (CaCTUS) and is one of only 9 in the UK cancer specific accredited units in the UK. In addition, CaCTUS is also a UK Clinical Research Collaboration (UKCRC) Registered CTU.  Further details of CTU activities can be found on the Unit’s website [www.crukctuglasgow.org](#).  The Clinical Trials Assistant (CTA) provides administrative and data management support to the clinical trial activity within the CTU. The CTA will directly support BWoSCC CTU Participating Activity, |

|  |
| --- |
| 5. **MAIN DUTIES/RESPONSIBILITIES**  The CRUK CTU has Standard Operating Procedures (SOPs) which all members of staff work to, ensuring uniformity. The department also adheres to 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.  The main duties and responsibilities of the CTA are to provide co-ordination and data management to allocated trials within their area of responsibility.  Providing co-ordination and data management to allocated non-CTIMP clinical trials that are run through the CRUK CTU. This involves:   * Checking that patient’s eligibility has been confirmed for a clinical trial by the Principal Investigator or their designee * Randomising/registering patients * Ensuring that investigations (e.g. blood tests, Quality Of Life Questionnaires) are carried out as per the study protocols. This involves close liaison with various members of the hospital staff from a wide range of departments * Review/extract data from hospital notes onto case report forms (CRFs) for patients on study and ensuring the data is accurate and up to date. CTAs must discuss the data collection with the clinician to ensure that information is documented to verify source data * Requesting and sending pathology samples for independent review. . In this case, the CTA is responsible for the labelling, packaging and couriering of these sample. The transfer of biological material is strictly regulated, and IATA guidelines have to be adhered to * Answering any queries that may be generated from the data collected within specified timelines. Clarification of the data must be discussed, and source data is updated by the clinician responsible for the study * Organising start-up visits for new studies, ensuring all the study personnel are in attendance (i.e. clinician, nurses, ) and all regulatory documentation is in place * Attending start-up visits, with the clinician responsible for the study to go through all the study procedures before any patients have been recruited * Working regularly with Sponsor representative responsible for monitoring study data. This would involve booking a monitoring area (if remote monitoring is requested, the CTA would book out a laptop) 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 arise   Provide assistance for Clinical Trial Coordinators (CTC)   * Assist with the maintenance of Investigator Site Files * Assist in the processing of amendments, tracking approvals and preparing documentation and updating the ISF and EDGE™ * Assist in the requesting of pathology samples or CT scan for independent review or provision to sponsor as required * Managing the archiving of study data, which involves sending, retrieving, and maintaining the archived study records. The CTU has regular archiving days, and it is the responsibility of the CTA to ensure all staff are archiving according to the Unit’s SOPs * The management of the CTU are required to oversee the reporting/processing timelines of SAEs that any BWoSCC clinical trial patient has. By law, SAEs must be reported by the responsible person within 24 hours of being made aware of the event. It is ultimately the responsibility of the Principal Investigator (clinician) at a site to report SAEs. The CTU maintains a log of all SAEs reported for BWoSCC patients. On a monthly basis, the CTA enters the details of all SAEs reported in the previous month on to EDGE™. These figures allow the CTU management to oversee the SAE reporting matrices and identify any issues or bottlenecks in SAE reporting * Within all clinical areas of the BWoSCC a telephone proforma system is in place to record any telephone communications with patients regarding their clinical management. The CTU has to review every telephone proforma completed to identify if the patient is currently on a clinical trial and if so, whether a SAE has occurred, if so, resulting in the requirement to report the event. The CTA is responsible for collecting the telephone proforma from all clinical areas (wards, day bed unit and out-patient department) daily, checking whether the patient is currently on a clinical trial, and where appropriate passing on to the appropriate CTC to report the SAE as required * Assisting the CTC with completing actions noted at routine monitoring visits * Assisting the CTC with audit preparation   **General:**   * Organising the maintenance of, and reporting issues of the CTU photocopier(s) to ensure that the machines run to maximum efficiency. The CTA is responsible for ensuring all staff use the equipment correctly and where required, arrange re-training of staff for use of equipment * The CTA is expected to follow departmental SOPs specific to their role. Where required the CTA will assist in the writing of any new SOPs and/or review of current SOPs to ensure that they adequately reflect the true processes followed * General office duties will include answering the telephone, photocopying and filing and any other duties necessary to help smooth the running of the trials unit |

|  |  |
| --- | --- |
| 1. **SYSTEMS AND EQUIPMENT**   The position involves the use of the following equipment and software: EDGE™ Database –The database is used to store information on all patients entered into clinical trials where the BWoSCC is a participating site. For our records, and safety purposes we can enter certain details of every patient entered into a clinical trial (amount of detail depends on the hospital the patient is being treated at). In certain trials, patients would be “randomised” by the database. This determines which treatment arm of the study the patient is assigned to. All data for studies co-ordinated from the department is entered onto the database. The database can generate queries on the entered data if data does not make sense, if certain investigation results seem excessive or inaccurate. EDGE™ can run multiple reports, ranging from outstanding data number of patients entered on a specific trial, workloads for CTCs/CTAs.Hospital Information System including Trackcare and the Clinical Portal - This is used for information on patient's appointments, admissions, to hospital and as a tracking system to locate case notes. Biochemistry, Haematology, Pathology, Radiology and Bacteriology information systems are used to obtain access to patient's results.Case Report Forms (CRFS) - Use to collect the data required for the study in a clear and precise format. Increasingly these are provided by the pharmaceutical companies as computerised eCRFs - eCRFs are completed as remote data entry on a web-based system, Electronic Data System (EDC). Specialised training in the function of the new system is required before the study can be opened to recruitment.Chemo Care - This is the hospital system used for prescribing patients’ chemotherapy. HEPMA – Hospital Electronic Prescribing and Medicines Administration Microsoft Office (MS Word, Outlook and Excel) – To Compile reports, provide summaries, type letters and protocols and for the general administration of the clinical trials Adobe Acrobat Reader - Allows conversion of documents created in other programs into Adobe to enable sending or comment and review as a PDF file    E-mail – To communicate with all people involved with clinical trials, circulate reports and information on studies. | |
| **7. DECISIONS AND JUDGEMENTS**   * The post holder will require minimal supervision and will be expected to organise their own workload and be proactive in their approach to the job * The CTA is responsible for ensuring all routine tasks are performed at the appropriate time point and in line with study deadlines, and that data entry within their area of responsibility is kept up to date in time with study deadlines. Where any requests are made by staff for any non-routine tasks to be carried out, the CTA is expected to prioritise workload accordingly * The CTA routinely handles patient’s medical files and can on occasion be asked to handle confidential paperwork therefore, discretion and confidentiality is required | |
| **8. COMMUNICATIONS AND RELATIONSHIPS**  The appointee will be expected to communicate and develop good working relations with the following bodies/people:   * All CTU staff * GGCHB Ethics Committee and Research and Development Department - to ensure that all necessary approvals for the study have been granted. The R&D department for the hospital now provide sponsorship for non-commercial studies run through the department * Pathology – close working relationships have to be established with pathology due to the increasing number of studies that require samples from patients surgery * BWoSCC Clinicians and other health professionals - 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 CTA may have to organise tumour samples, copy scans or blood reports to be sent away for independent review * Research nurses– All Phase I and the majority of Phase II studies have research nurses allocated to them. CTAs may be their main point of contact for any queries regarding the study treatment or scheduling of investigations. Working closely with research nurses is essential when they are performing assessments as per protocol for the study * Medicines and Healthcare Products Regulatory Agency (MHRA) – in accordance with the EU Directive, the MHRA is the Competent Authority of the UK. All studies have to have a Clinical Trials Authorisation if they involve an IMP (Investigational Medicinal Product) – this is a legal requirement. The MHRA have to be informed of all SAEs/SUSARs, any other safety issues arising, and any protocol amendments * Pharmaceutical companies - All data collected for any study must be monitored regularly. Visits to the department are scheduled to have all CRF’s audited ensuring that the data is accurate. Telephone calls, faxes or e-mails requesting data clarifications and patient updates are also common place. This may involve discussion between CTA, Sponsor, and clinician * Site staff and study teams participating in trials coordinated by the CRUK CTU | |
| **9. PHYSICAL DEMANDS OF THE JOB**  The physical demands of the job are those to be expected in any normal office environment.  Approximately 80% of time is spent working at the computer requiring excellent keyboard skills. The other 20% is spent between filing, photocopying, and other non-desk-based activities. Filing can require stretching to reach files on shelves and lifting of heavy files. Space for filing can be limited which means working with very little work space and no room to walk around.  Data for all closed studies is eventually archived off site. This involves disposal of all non-essential documentation, condensing the CRF files weighing and lifting heavy boxes. These boxes can weigh up to 15kg.  High level of concentration is required for accurate information entry on databases and CRFs.  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. | |
| **10. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB**  The most challenging aspect of the work is multi-tasking and prioritising between several simultaneous projects, ensuring that each maintains a forward momentum. As outlined, there can be over 160 open clinical trials in the Unit at any one time as well as all the closed trials.  Require flexibility to address wide degree of variability in workload. This can be particularly challenging when a number of the trials all require administrative input as a priority at the same time. | |
| **11. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB**   * Relevant HND qualification or equivalent experience * ICH GCP Training * Good knowledge of medical terminology * Minimum of 3 years administrative experience supporting and working as part of a team – ideally within the NHS * Experience of managing a diverse and continuously changing workload * Excellent organisational skills and the ability to work to strict deadlines * Excellent communication skills (oral and written) * Excellent IT and keyboard skills and a practical knowledge of the use of MS Office applications * Ability to work under pressure to ensure deadlines are met * Excellent interpersonal skills, flexibility and the ability to work in a team or by oneself * Experience of working in a clinical trials environment is desirable but not essential as training is provided | |
| **12. 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:**  **Head of Department Signature:** | **Date:**  **Date:** |