Mater Misericordiae University Hospital

CNM2 Infusion Nurse

START Dublin
(Early Phase Oncology Clinical Trials Unit)

Recent years have seen astonishing and rapid advances in the understanding and treatment of cancer. Technological innovations have resulted in more rational drug design, bringing hope of better treatments to patients who have been diagnosed with advanced cancer, but who may have stopped benefitting from traditional treatments such as chemotherapy. For Irish patients it is difficult however to gain access to the cutting edge of drug development and accessing new drugs is a serious issue for patients and doctors in this country. To address this, the Mater hospital has partnered with The START Centre for Cancer Research, one of the global leaders in early phase oncology clinical trials. Early phase (or Phase 1) trials are where new and exciting drugs are first evaluated in patients for safety and the first signs of efficacy. START Dublin is Ireland's first and only Phase 1 clinical trial site and is physically located at and operated by The Mater Hospital. This exciting venture will meet a national need, giving our patients the opportunity to access exciting and innovative drugs that they would not otherwise be able to access in the context of a well-run and closely monitored program.

Job Title/Grade:

CNM 2 Infusion Nurse START Dublin

Directorate:

Cancer Directorate

Department:

START Dublin Phase 1 Clinical Trials Unit

Reporting Relationship:

Professional Issues: Assistant Director of Nursing (ADON) START Dublin / Directorate Nurse Manger (DNM) Cancer Directorate

Patient & Clinical Issues:
Assistant Director of Nursing (ADON) START Dublin / Director of Clinical Research START Dublin

Job Description:

- The CNM2 will provide professional and clinical leadership and support to the nursing team at START Dublin.
- The CNM2 is responsible for providing direct patient care to individuals who are participating in clinical trials conducted at START Dublin.
- The CNM2 uses appropriate professional judgment and decision making in planning and providing care. Nursing care is to be delivered in a manner consistent with the Standard Operating Procedures (SOPs) and professional evidence-based standards in the Mater Misericordiae University Hospital (MMUH).
- The CNM2 will coordinate and manage nursing resources within START Dublin.
- The CNM2 will be an integral part of a multi-disciplinary team, engaging with researchers and clinicians to support clinical research within START Dublin.
- The CNM2 will work closely with the ADON and Medical Director in the strategic planning and provision of services to this unit.
- The CNM2 will work with the ADON, DNM and Medical Director to determine an integrated nursing development strategy to support practice and research in START Dublin.

- The CNM2 will be responsible for staff development and support for the nursing team in START Dublin.
- Communicate effectively with the START Dublin team, colleagues in the other START sites, based both in the EU and US and the MMUH Cancer Directorate team.
- The CNM2 will participate in education and training of new staff in the unit to achieve and maintain clinical competencies pertinent to the service.
- The CNM2 will participate in the internal and external audits to assess the quality of the service being provided.
- The CNM2 will participate in developing policies, SOPs and work instructions to maintain the highest standard and quality of work done.
- The CNM2 will assist the ADON in ensuring that all studies are conducted to the highest standards in accordance with ICH/GCP (R2), clinical trial regulations and in keeping with local regulatory requirements.
- The CNM2 will also have a responsibility for a caseload of patients on clinical trials.

Requirements:

- Must be registered with the General division of the Nursing and Midwifery Board of Ireland (NMBI).
- Have a minimum of 5 years post registration and 4 years' experience in a relevant Cancer Nursing setting.
- Post graduate qualification in adult Cancer Nursing desirable.
- Competent in the administration of Systemic Anti-Cancer Therapy essential.
- Experience in the administration of Investigational Medicinal Products desirable.
- Experience in nursing care of patients participating in clinical trials desirable.
- Excellent oral and written communication skills essential.
- Excellent management and interpersonal skills essential.
- Demonstrate ability to work as part of the research team and as part of wider multidisciplinary team.
- IT skills including Microsoft Office Suite desirable.
- Have proven clinical skills e.g be competent in phlebotomy, cannulation procedures.
- Prior ICH-GCP (R2) training desirable.
- Advanced Cardiovascular Life Support desirable.

General Responsibilities:

- In relation to professional nursing issues report directly to the ADON START Dublin/DNM Cancer Directorate.
- In relation to clinical, patient and research related issues report to ADON START Dublin and Medical Director START Dublin.
- Work in collaboration with the other members of the START Dublin team and relevant clinical and multidisciplinary team members.

- Ensure strict adherence to hospital policies and procedures.
- Ensure strict adherence to department SOPs to ensure protection of patient rights, interests and wellbeing.
- Undertake training in GCP/ICH (R2).

Specific Responsibilities:

- Work closely with the ADON START Dublin to develop a strong team ethos within the START Dublin team.
- Attend various requisite meetings including weekly team meetings to discuss patients on study and their progress, planning and preparation for the week ahead, patient referrals, and weekly protocol review meetings where current and future trials are discussed.
- Provide a high level of professional, clinical leadership and support to the START Dublin clinical team.
- Participate in the development and implementation of strategic plans for START Dublin in collaboration with the Medical Director and ADON START Dublin.
- Ensure adherence to ICH-GCP (R2) guidelines, and GDPR legislation.
- Administers Investigational Medicinal Products and/or chemotherapy/biotherapy to patients according to the protocol and applicable regulations.
- Performs study related activities such as venepuncture, obtaining blood specimens, IV insertion, venous access device management, holter placement, recording of ECGs, and obtaining vital signs.
- Collects and processes biological samples according to the protocol and relevant SOPs.
- Manages pharmacokinetic samples in line with study protocol and manages the pharmacokinetic laboratory.
- Review proposed clinical trial protocols and provide input into site feasibility reports.
- Attend Investigator meetings as relevant.
- Attend Site Initiation Visits.
- Work closely with clinical colleagues ensuring best practice across the clinical pathway, be seen as a knowledge base and key resource for the START Dublin nursing team and nurses working in cancer care.
- Liaise with the Acute Oncology/Haematology triage service and St. Vincent's Inpatient Oncology/Haematology ward and arrange follow up of patients who have called the triage service.

Managerial Role:

- Provide good clinical leadership and vision and facilitate team building.
- Develop a shared sense of commitment and participation amongst the nursing team about change management in response to the current and future needs of START Dublin.

- Manage and develop personnel functions to improve staff morale and maximise the recruitment and retention of nursing staff in START Dublin.
- Arrange and ensure training and education as appropriate for the nursing team in relation to clinical trials.
- Contribute to service development through appropriate continuous education, research activities, keeping up to date with clinical trial outcomes and study releases.
- Circulate and cascade relevant information and clinical trials protocol updates in line with regulatory and ethics requirements to the team members assigned study specific duties.

Patient Management:

- Administer Investigational Anti-Cancer drugs in the Treatment Room
- Organise patient treatment schedules in collaboration with the Patient Scheduler/Navigator and ensure all required tests, procedures and assessments are performed in accordance with the protocol requirements during screening, treatment and follow up period.
- Discuss study participation with patients and their families ensuring the informed consent process is adhered to.
- Ensure patient confidentiality and dignity is assured and always maintained during a clinical trial.
- Educate patients and their families on treatment schedules, potential benefits and side effects in accordance with clinical trial protocol.
- Enrol eligible patients to clinical trials in accordance with study protocol.
- Review patients at treatment visits ensuring all protocol related assessments are conducted in compliance with the clinical trial protocol.
- Ensure that the dignity, health, safety, and welfare of patients are always given the highest priority.
- Utilise skills, knowledge, nursing diagnosis, and clinical judgement to provide a high standard of care for patients in clinical trials.
- Utilise nursing assessment skills to observe participant general well-being and potential adverse events. Documents events and takes appropriate action as needed.
- Respond to emergency situations based upon MMUH nursing standards.
- Review patients in study follow up at clinic visits ensuring all protocol related assessments are conducted in compliance with the clinical trial protocol.
- Ensure blood and tissue samples are obtained, processed, stored and shipped to central facilities in accordance with the clinical trials protocol.
- Maintain stock control of treatment room and clinical trial supplies.

Study Coordinator Responsibilities:

- Will be courteous and polite in both written and verbal communication, expressing as well as communicating ideas in a non-confrontational manner in one-on-one situations, small groups, larger audiences, email communication, etc.
- Communicates on a regular basis with study Sponsors, central research team, staff, etc. regarding questions, concerns, and status of the protocol.
- Will have regular and timely communication with each Clinical Research Associate (CRA) involved with assigned protocols.
- Management of protocols.
- Will monitor the overall day-to-day conduct of assigned studies in accordance with the specified protocol requirements, SOPs, and GCP to ensure integrity regarding all aspects of the study.
- Reviews forms and flow sheets created or revised for assigned trials to assure protocol compliance.
- Maintains files using standardised study document labeling and filing procedures.
- Implements initial protocol and amendments, training staff who will be involved in patient treatment and management.
- Maintains an up-to-date contact list.
- Assists with patient screening and determination of eligibility.
- Facilitates the informed consent process ensuring that consent is appropriately completed.
- Prepares and manages source documents according to SOPs.
- Will recognise deviations to the protocol and will work with management and staff to address corrective actions to prevent deviations.
- Will assist CRA with case report form completion and query resolution.
- Will work with the Investigator to complete and submit Serious Adverse Event reports.
- Is responsible for all protocol specific closeout related activities in conjunction with the CRA.
- Will provide documentation for all deviations.

Training and Education:

- Ensure all hospital mandatory training is up to date.
- Ensure compliance and maintain up to date training in line with ICH-GCP (R2), regulatory requirements and SOPs.
- Attend Investigator meetings and Site Initiation Visits as required.
- Study and be familiar with the clinical trial protocol and have a clear understanding of its objectives and requirements.

- Study and be familiar with user manuals and vendors for central laboratory blood and/or tissue testing, and imaging transmission etc.
- Educate and train oncology/haematology clinical staff within the service on the clinical trial protocol and the objectives.
- Display evidence of continuing professional development.

Personal development:

- Maintain professionalism at all times and adhere to the code of conduct as laid down by NMBI.
- Foster good working relationships with all members of the clinical team, which are both professional and supportive.
- Accept responsibility for own personal professional development and to be aware of current trends and strategies in nursing particularly those that are relevant to providing the highest standard of support and care to patients with cancer.
- Accept responsibility to develop management skills.
- Attend courses and conferences as appropriate to speciality and disseminate information gained with colleagues as appropriate.

General Responsibilities and Accountabilities:

1. **Confidentiality**
   You will be aware of the confidential nature of Hospital work, and particularly the patients right to confidentiality.
2. **Policies & Procedures**
   You are required to familiarise yourself with and adhere to all policy and procedural documents relevant to your position.
3. **Hygiene Standards**
   The highest standard of hygiene must be maintained in the hospital at all times, and all staff members are responsible for ensuring compliance with the hospitals requirements and standards with regard to hygiene. It is the responsibility of all staff to have a fundamental understanding of their individual responsibility in maintaining departmental and site hygiene standards.
4. **Health and Safety**
   Ensure that effective safety procedures are in place to comply not only with the Safety, Health and Welfare at Work Act 2005 but also within the spirit of the hospital's mission, vision and values, and they are known and followed by staff. You are required to familiarise yourself with the requirements of employees under the Safety, Health and Welfare at Work Act 2005 and to promote a work environment that is compliant with the

Safety, Health and Welfare at Work Act 2005. Each staff member is individually responsible for ensuring that the Hospital remains a safe place to work.

5. **Information Technology**
   Ensure the most effective and efficient use of developments in information technology for administrative support in a manner which integrates well with systems throughout the organisation.

6. **Business Continuity Management**
   Business Continuity Management is a holistic management process that identifies potential impacts that threaten an organisation and provides a framework for building resilience and the capability for an effective response that safeguards the interests of its key stakeholders and reputation (BS 25999). All staff employed in the Mater Misericordiae University Hospital are obliged to:

   - Make themselves familiar with the Organisational Business Continuity Plan
   - Attend Business Continuity Management education sessions provided for them
   - Make themselves familiar with their individual roles as set out in their departmental business continuity plan if applicable and or the Organisational Business Continuity Plan

Note:
These duties and responsibilities reflect the present service requirements and may be subject to review and amendment to meet the changing needs of the unit.

Professional Qualifications/Experience:

Essential:
Eligible applicants will be those who on the closing date for the competition are:

- Be a Registered General Nurse with the NMBI or entitled to be so registered.
  and
- Have a broad base of clinical experience relevant to the advanced field of practice with a minimum of 5 years post-registration experience, which will include 4 years' experience in the chosen area of specialist practice.
- Be competent in the administration of systemic anti–cancer therapy

Desirable:

- Possess a Level 8 qualification in Cancer Nursing.

- Clinical Trial experience