

Job Title & Grade	Senior Clinical Trials Pharmacist – Haematology-Oncology Clinical Trials
Campaign Reference #	47452
Closing Date	19 th June 2023 at 5 pm
Duration of Post	Specified Purpose Contract – Maternity cover
Specific T&C's	35 hours standard working week
of post	29 days Annual Leave
	Remuneration is in accordance with the salary scale approved by the Department of Health:
	Current salary scale with effect from 1st October 2022 Grade 3239 .Rising in increments
	annually from Point 1 €57, 450 €71,011 €72,010 €73,004 €73,126 €74,517 €76,049 €78,
	728
Location of	CHI Crumlin
post	
Reporting	This post will report to the CHI Head of Pharmacy Services or his/her deputy.
Arrangements	
Key Working	The post holder will work closely with:
Relationships	Principle Investigators (PI) for Haematology-Oncology clinical trials
	Research and Innovation Office / Research Management Team
	Cancer Clinical Trials Unit staff
	Healthcare staff providing support to clinical trials services, such as research nurses
	Pharmacy Department
	Please note that this list is not exhaustive and key working relationships will change as the project moves from service development, construction completion, commissioning & transitioning to steady state.
Purpose of the Role	This position is to support Clinical Trials of an Investigational Medicinal Product (CTIMPs) in children's cancer services in CHI at Crumlin and ensure compliance with current national legislation as well as the International Conference of Harmonisation Good Clinical Practice (ICH GCP).
	The post holder will provide pharmaceutical advice and support development of the Clinical Trial Pharmacy Service, in order to optimise patient benefit from treatment with medicines and ensure the safe, efficacious and cost-effective use of medicines. The post is critical to



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ensure the provision of a quality pharmaceutical dispensing and aseptic service to patients cared for by the hospital with regard to clinical trials.

Principal Duties and Responsibilities

Professional Duties and Responsibilities:

- The post holder will be expected to live CHI values and be child-centered, compassionate, progressive and will act with respect, excellence and integrity.
- Develop and maintain policies, guidelines and standard operating procedures (SOPs) for the general operation of CTIMPs in cancer services in CHI at Crumlin.
- To have a good working knowledge of GCP, GMP and all procedures, legislation or national guidelines relating to aseptic preparation and dispensing of medication for clinical trials of Investigational Medicinal Products.
- Review CTIMP protocols that are proposed to open and conduct a feasibility assessment from the point of view of pharmacy services, legislation and GCP.
 Identify all challenges that operating the proposed protocol may bring and communicate same to the local PI, line manager and CCTU. Work to resolve and mitigate such challenges where possible.
- Assist CCTU staff in preparation of Clinical Trials Applications for CTIMPs for submission to HPRA
- Develop supporting documentation for each clinical trial, such as SOPs, training records, etc as well as documentation that supports the operation of the trial e.g. medication advice charts if required.
- Participate and assist in processes designed to facilitate the opening, running and closure of clinical trials e.g. site initiation visits, monitoring visits, closing meetings
- Train pharmacy colleagues in clinical trials SOPs and related relevant documentation.
- Ensure IMPs are ordered, stored and dispensed in accordance with the clinical trial protocol, ICH-GMP and other relevant documentation. Ensure accountability logs are maintained as appropriate.
- Facilitate clinical research associate (CRA)-led site monitoring exercises. Effectively communicate and work to resolve all discrepancies and queries that may arise.
- The post-holder must ensure that they keep abreast of all clinical trial protocol updates, update associated SOPs and documentation and then communicate all changes to relevant personnel.
- Collaborate with colleagues involved in the building and running of the electronic cancer management system e.g. NCIS, to support the inclusion of clinical trial regimens in the system.

Pharmacy Department



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- Support the supply of medications to wards and clinical departments in the hospital in line with legal requirements and hospital policies
- Dispense or supervise the dispensing of prescriptions and extemporaneous preparations as may be required
- Provide appropriate patient counselling
- Provide medicines information as may be requested
- Attend Pharmacy Team meetings
- Support the development of medicines management policies, protocols and guidelines as appropriate
- Participate in training programmes on medication safety and medication management for Pharmacy and other hospital employees.
- Support pharmacy staff training as appropriate

Education/Continuous Professional Development:

- Maintain standards of professional knowledge through personal study and attendance at appropriate courses and conferences
- Be self-directed in terms of learning and professional development
- Ensure all organisational mandatory training is undertaken at the specified intervals
- Undertake regular ICH-GCP training, as per institutional policy

All duties will be carried out in accordance with GCP guidelines, all relevant research and hospital policies and all applicable laws and regulations for the conduct of clinical research.

The above is not intended to be a comprehensive list of all duties involved and consequently, the post holder may be required to perform other duties as appropriate to the post which may be assigned to them from time to time and to contribute to the development of the post while in office.

Eligibility criteria, qualifications and experience

Essential Criteria:

- Registered Pharmacist with the Pharmaceutical Society of Ireland, or be entitled to be registered
- At least three years' post qualification experience
- Possess the requisite knowledge and ability (including a high standard of suitability) for the proper discharge of the duties of the office.

Desirable Criteria:

- Experience of working in paediatrics, haematology-oncology, clinical trials or other related disciplines
- Experience of conducting and managing clinical trials



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Competition Specific Selection **Process**

Applications for this post must be accompanied by a cover letter, setting out relevant experience that illustrates how the essential criteria listed above is met.

The criterion for short listing is based on the requirements of the post, as outlined in the eligibility criteria.

How to Apply & Informal **Enquiries**

* Please note that you must submit a cover letter with your CV, this forms part of your application and CV's will not be accepted without a detailed cover letter.

The closing date for submissions of CV's and cover letter is 19TH June 2023 by 5pm. Applications must be completed through the advertised post on CHI.jobs by clicking 'Apply for Job'.

Applications will not be accepted through direct email or any other method.

For informal enquiries for this specialty/department, please contact Eileen Butler at Eileen.butler@olchce.ie

For other queries relating to this recruitment process, please contact Victoria Gsamelova at Victoria.gsamelova@nchg.ie

Information on "Non-European Economic Area Applicants" is available from https://dbei.gov.ie/en/

The programme outlined for Children's Health Ireland may impact on this role and as structures change the job description may be reviewed.

Children's Health Ireland is an equal opportunities employer.