 

**Vigilance Officer**

**HRB Clinical Research Facility, Galway**

**NUI Galway.**

**Ref. No. NUIG 001-20**

Applications are invited from suitably qualified candidates for a fixed-term contract position as a Vigilance Officer within the HRB Clinical Research Facility at the National University of Ireland, Galway (CRFG). The position is available immediately for a period of one year, with potential to extend subject to project success and funding acquisition.

The HRB Clinical Research Facility, Galway’s (CRFG) remit is to increase the amount of clinical research currently undertaken in Ireland. Medical doctors and nurses will work with other scientists to improve our understanding of a variety of diseases and to develop new tests and treatments to help tackle these diseases. The Centre aims to provide patients with the latest advances in areas such as Cancer, Obstetrics and Gynaecology, Diabetes, Inflammatory Diseases, Critical Illness, Cystic Fibrosis, Cardiovascular Disease, Psychiatry, Gastroenterology, Renal Disease

Please see [www.crfg.ie](http://www.crfg.ie/) for more information on the facility.

**Job Description:**

The Vigilance Officer role is part of a multi-disciplinary team within the CRFG co-ordination unit. The Vigilance Officer will establish and maintain Device Vigilance or Pharmacovigilance processes that support the activities of the HRB-CRFG as a delate Sponsor in relation to Clinical Trials and Clinical Investigations, while being the primary point of contact for queries and issues related to Sponsor oversight functions. The role will establish safety oversight processes for clinical trials of medicinal products/medical devices across all study phases.

The Vigilance Officer supports the associated study teams in ensuring Adverse Event and device deficiency reports are processed in an accurate and timely fashion in accordance with regulatory requirement; and ensures that NUIG is informed in a timely and accurate fashion of safety issues concerning NUIG-Sponsored trials, to safeguard the interests of patients and health-care professionals while complying with legal/regulatory requirements concerning adverse event monitoring and reporting.

The Vigilance Officer manages the overall evaluation of pharmacovigilance data received and identification of potential pharmacovigilance issues; implements Risk Management strategies in the HRB-CRFG and NUIG, to ensure NUIG-adopted studies are appropriately monitored in terms of safety and onward reporting; and develops, implements and maintains systems to assure the quality of institutional-sponsored clinical research undertaken within the HRB-CRFG is in accordance with all relevant regulations and standards.

**Duties:**

* Interpret complex legislation as applies to Sponsoring clinical research studies, identifying the implications for HRB-CRFG operation and act to initiate necessary changes to practice in order to ensure that the HRB-CRFG remains compliant with statutory regulations at all times.
* Maintain systems and processes to ensure that Pharmaco/device vigilance practices for Sponsored clinical studies that are run through the HRB-CRFG are conducted in accordance with ICH GCP guidelines, the Clinical Trial Directive, the relevant medical device directive ISO 14155 and all relevant legislation and standards.
* Liaise with the sponsor to ensure that all requirements are met in terms of safety monitoring, assessment and onwards reporting.
* Develop mechanisms for Risk Assessment of sponsored clinical studies from the point of view of Pharmacovigilance to ensure that any high risk areas are mitigated prior to the study opening and throughout the course of the study.
* Guide and assist with the production of periodic safety update reports (e.g. DSUR) and other interim reports as required (e.g. DSMB).
* Undertake periodic safety reporting to all relevant Regulatory Authorities.
* Prepare and send periodic progress reports to the Sponsor.
* Undertake EudraVigilance registration as required.
* Act as the Pharmacovigilance contact person for Sponsor-affiliates, internal staff and project managers.
* Provide professional advice to CIs/PIs in relation to safety monitoring and reporting in the conduct of clinical research.
* Handle collection, submission and filing of safety data from study event reports, spontaneous reports and reports from literature for studies where the Sponsor these duties.
* Lead with the preparation and maintenance of Pharmacovigilance documentation and SOPs.
* Liaise with Clinical Research personnel in the preparation of safety data required in support of the clinical research programme.
* Respond to all medical and technical enquiries accurately and in accordance with current opinion/knowledge, the published literature and HRB-CRFG in-house expertise.
* Ensure that all medical information queries from both NUIG/HRB-CRFG and external stakeholders are handled accurately and in a timely manner.
* Maintain regular contact with external personnel reporting adverse drug reactions or making medical information enquiries and with regulatory authorities as required, in addition to both NUIG and HRB-CRFG associates.
* Provide NUIG-wide quality assurance activities aimed at monitoring and improving regulatory compliance for both clinical research and pharmacovigilance.
* Undertake continuous monitoring and review to ensure accuracy and quality of output processes.
* Maintain references and other Medical Information resources.
* Provide Pharmacovigilance training to internal staff, and external partners, as required.
* Budget development support for Device vigilance or pharmacovigilance.
* Carry out other appropriate and relevant duties under the direction of the CRFG Director/sponsor that arise during the ambit of the post.

**Qualifications/Skills required:**

**Essential Requirements:**

* Degree level qualification in a clinical or life sciences related subject.
* Proven project management and organisational skills.
* Five years’ experience gained working in clinical research or a closely related field in the commercial setting (e.g. CRO, Pharma or Medical Device sector) or in an academic setting.
* Must have experience gained working in a vigilance role (Pharmaco or Device vigilance) for a sponsor in a commercial (e.g. CRO, Pharma or Medical Device) or academic setting.
* Experience in developing vigilance strategies and safety data management.
* Excellent communication skills (oral, written & presentation) with proven ability to work effectively as part of a team.
* Strong leadership and communication skills.
* Self-motivated and able to work independently, showing initiative and good judgement.
* Good data management and IT skills.

**Desirable Requirements:**

* At least one year experience gained working directly in a vigilance role (Pharmaco or Device vigilance) for a sponsor in a commercial (e.g. CRO, Pharma or Medical Device) or academic setting.
* Qualification in Pharmacovigilance or related discipline leading the development of safety plans and strategies for safety oversight of clinical study execution
* Postgraduate Qualification in Clinical Research or other Life Science or engineering-related subject
* Prior experience in Pharmacovigilance of academic-Sponsored clinical studies
* Understanding of MedDRA and device vigilance coding
* Familiarity with medical and therapeutic area knowledge terminology
* Understanding of EudraVigilance and EUDAMED reporting processes.
* Clinical Research Data Management experience
* Experience working with EDC systems for data capture and design of Safety Case Report Forms.
* Good Clinical Practice training

**Salary**: €54,717 - €71,430 per annum.

**Start date**: Position is available immediately.

**NB**: Gárda clearance is a requirement for this post

**Continuing Professional Development/Training**:

Researchers at NUI Galway are encouraged to avail of a range of training and development opportunities designed to support their personal career development plans.

Further information on research and working at NUI Galway is available on [Research at NUI Galway](http://www.nuigalway.ie/our-research/)

For information on moving to Ireland please see [www.euraxess.ie](http://www.euraxess.ie)

Further information about our centre is available at [www.crfg.ie](http://www.crfg.ie)

**To Apply:**

Applications to include a covering letter, CV, and the contact details of three referees should be sent, via e-mail (in word or PDF only) to grainne.macnamara@nuigalway.ie

Please put reference number **NUIG 001-20** in subject line of e-mail application.

**Closing date for receipt of applications is 5.00 pm 31st January 2020.**

**A panel may be formed for future similar posts.**

All positions are recruited in line with Open, Transparent, Merit (OTM) and Competency based recruitment

National University of Ireland, Galway is an equal opportunities employer.