Research Fellow: Senior Clinical Trial Coordinator/Project Manager

CORRIB Research Centre for Advanced Imaging and Core laboratory

Ref. No. University of Galway 264-22

Applications are invited from suitably qualified candidates for a full time fixed-term contract position of 2 years initially as a **Research Fellow: Senior Clinical Trial Coordinator/Project Manager** within a thriving Academic Research Organisation. The position may be extended with additional funding availability. The position is available immediately.

The role will take the lead as project manager on a Multi-country, multi-centre IIS Medical device study and will also lead as required on key strategic priorities and programme and study level study activities within the CORRIB unit.

The post-holder will join the Cardiovascular Research Centre for Advanced Imaging and Core Lab (CORRIB) which is a newly established centre of excellence for innovation, research, collaboration and education in Cardiovascular research in the National University of Ireland, Galway, Ireland in collaboration with several medical and biomedical institutions and centres at University of Galway [http://www.universityofgalway.ie/corrib-corelab/].

The Senior Clinical Trial Coordinator works under the direction of the CORRIB Research Team Directorship/Clinical Trials Operations Lead/ Clinical Trials Programme Manager to co-ordinate and operationalise studies within the unit.

This is a lead project coordination and management role within the coordination unit of the ARO and the post holder has a senior level coordination role leading research studies, clinical trial(s) or clinical investigation(s) throughout the study lifecycle of set-up, execution, close-out and reporting in addition to mentoring coordination personnel in the unit.

The Senior Clinical Trial Coordinator supports the programme to ensure that the studies coordinated in the ARO coordination team are in line with Good Clinical Practice (GCP) and/or ISO 14155, internal SOPs and policies and relevant legislation and regulatory requirements.

The role acts at a senior level within the team and involves mentorship of clinical trial coordination team(s), involving tutoring and training of more junior or less experienced coordinator team colleagues. Where appropriate the role will act as project leader and as a line manager of research teams as required

Job Description:

- Responsible for the overall leadership and management of Multi-country, multi-centre IIS Medical device clinical research project, taking the lead as project manager on this multisite, multicountry, international clinical trial.

- Lead and development of key strategic priorities and programme and study level study activities within the CORRIB unit.
- Lead and manage one of Corrib's major research grants, liaising with the Chief Investigator, Clinical Trials Operations Lead and Clinical Trials Programme Manager as required.
- Lead on any budget agreements and contract negotiation as required for the trial, leading on negotiating budgetary change order for additional funding if required.
- Lead on the overall regulatory strategy for the study in line with MDR 2017/745, ISO14155 and GDPR requirements with input from local regulatory experts across Europe for the trial.
- Project lead for one of Corrib's main full service multi site multi country trial and lead the project research team, acting as the driver of the research project and outputs.
- Will have full operational responsibility for the project.
- Co-ordinate the work of the project research staff. Organise and conduct meetings with research staff to clarify objectives, develop work plans/timetables for research and support staff and communicate progress
- Play a leadership role for junior colleagues in the study organisation and in the Corrib unit.
- Managing the publication portofolio to ensure research dissemination.
- Contribute to the development of multisite multicountry clinical trial research strategy within CMNHS and University of Galway.
- Able to manage and oversee research projects and to take responsibility for their overall success. Take responsibility for, manage and conduct administrative and management tasks associated with your programme of research
- Play a leading role/is active in external networks or professional organisations, to identify sources of funding, generate income, obtain consultancy projects, or build collaborative relationships for future activities.
- Undertake periodic landscape review for legislative requirements and implement processes to incorporate changes into existing systems or introduce new processes to ensure regulatory compliance.
- Leadership in the development and setup of appropriate clinical trial co-ordination processes, SOPs and associated templates to guide the successful and standardised execution and delivery of clinical trials in the ARO co-ordination unit.
- Oversee and ensure key study milestones and objectives are tracking to an agreed timeline and adhere to project management best practices, promoting a best practice culture and leading on project management techniques within the facility.
- Lead the development and execution of study plans including leading the establishment of project plans, risk assessments and management and planning resources.
- Confirm the necessary processes are in place for management of the investigational product, as applicable and other study supplies.
- Lead the process of protocol development, where applicable and design and support quality by design.
- Lead on the development of study monitoring strategies taking into account risk based approaches where applicable.
- Provide an advisory role and participate in the process of developing study related documentation such as CRFs, SOPs, information sheets, risk assessments, their amendments and associated quality assurance processes and documents as required for applicable studies.
- Lead the process to identify and procure vendors/suppliers or service providers, vendor/service provider assessment, and undertake any associated computer system validation requirements.
- Responsible for coordinating the process of institution(s), Regulatory and Ethics Committee approvals submissions, as applicable.
- Lead on investigator and site evaluation and selection processes.
- Oversee the process of study initiations, site training, monitoring and close-out as required.
- Liaise directly with clinical sites as required to aid resolution of queries that arise and provide direction on implementation and management of the study protocol and procedures, and provide direction to coordination unit colleagues as applicable.

- Implement systems to ensure compliance with all applicable regulations and guidelines, ARO coordination level SOPs and/or ARO site SOPs as required.
- Lead preparation for audits and inspections as required and present work as required during audits and inspections.
- Lead preparation of study and coordination unit summary reports as required.
- Provide training as appropriate on study-related activities and processes for site personnel.
- Provide training as required for new personnel undertaking co-ordination tasks.
- Update sponsor, Chief Investigator, data and safety monitoring committees, regulatory bodies, ethics committees, and other governing bodies on the status of all clinical trial activities.
- Implement strategies, support and lead as required, initiatives for participant recruitment for research studies as required.
- Undertake clinical data compilation and literature reviews for the research area and participate in dissemination of same at international meetings.
- Determine appropriate methodologies and activities for relevant research studies in the ARO whilst keeping up to date with research related methods and techniques.
- Contribute to manuscripts for publication to peer reviewed internationally recognised journals.
- Contribute to the dissemination of knowledge in the ARO and facilitate research activities such as workshops and screening events.
- Continue to build personal skills by taking training opportunities as available and required.
- Carry out other appropriate and relevant duties under the direction of the CORRIB Research Team Directorship/ Clinical Research Operations Lead/Clinical Trials Programme Manager.

Qualifications/Skills required:

Essential Requirements:

- Primary/Master's Degree level qualification in a clinical or life sciences related subject.
- Minimum of 4- 6 years' post qualification experience gained working in clinical research or a closely related field e.g. Pharma or Medical Device sector.
- Have an established reputation for the quality of their research work.
- Independent researcher with experience leading significant research project(s)/teams
- Demonstrate extensive experience of initiating, designing and implementing research projects/teams.
- Possess sufficient breadth or depth of specialist knowledge in the discipline to act as a research leader and have the ability to project manage major projects. Previous experience gained in a medical device clinical trial co-ordination unit (Commercial CRO or ARO) organisation delivering coordination services for device trials is required for this role with experience gained in any or all of the following: (a) clinical trial co-ordination/project or site management (b) clinical trial monitoring role (c) clinical trial data management role or (d) safety management.
- Experience in operational delivery of multisite studies.
- Experience working within a Quality Management adhering to QC and QA control systems and risk management processes.
- Experienced in leading and establishing new processes.
- Strong project management skills and ability to take the lead on the delivery of key project milestones.
- Leadership and mentoring skills.
- Excellent verbal and written communication/presentation skills.

Desirable skills:

- Post graduate level qualification in a clinical or life sciences related subject.
- A Project management qualification.
- Experience adhering to applicable regulations, guidelines and legislation for Clinical Trials.
- Previous experience gained project managing a cross functional project team.
- Experience in management of cardiovascular device trials.

- Experience with data management, safety management, clinical trial monitoring processes including the identification, assessment and management of risk.
- Self-motivated, high level of initiative and excellent attention to detail.

Salary: Research Fellow €56,933 - €74,322 per annum pro rata for shorter and/or part time contracts (public sector pay policy rules pertaining to new entrants will apply).

Start date: Position is available immediately.

Continuing Professional Development/Training:
Researchers at University of 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 University of Galway is available on Research at University of Galway

For information on moving to Ireland please see www.euraxess.ie

Further information about our centre is available at http://www.universityofgalway.ie/corrib-corelab/

Further information about Corrib Core Lab is available in the attached brochure

BM Core Lab
Portfolio brochure v

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 CorribCLABfinance@universityofgalway.ie

Please put reference number **University of Galway 264-22** in subject line of e-mail application.

Closing date for receipt of applications is 29th November 2022 at 5.00 pm

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

University of Galway is an equal opportunities employer.