OLLSCOIL NA GAILLIMHE
UNIVERSITY OF GALWAY

HR EXCELLENCE IN RESEARCH

Research Associate - Clinical Research Data Manager

HRB Clinical Research Facility Galway (CRFG)

School of Medicine

Ref. No. 011785

JOB ADVERTISEMENT

Applications are invited from suitably qualified candidates for a full-time specific purpose contract as a Clinical Research Data Manager (Research Associate grade) with the HRB-Clinical Research Facility Galway (HRB-CRFG) team at the University of Galway. This position is available immediately to support the work currently being undertaken within the unit.

This position is funded by clinical research studies and is available for 1 year initially, with the potential to extend subject to project success and further funding acquisition.

The Biostatistics and Data Management Hub within the HRB-CRFG, a constituent unit of the Institute for Clinical Trials, includes both an extensive biostatistics service and the provision of an integrated clinical data management service. This means seamless clinical data capture, validation, monitoring, storage, processing and archiving powered by the latest clinical research data management technology. The Clinical Research Data Manager will interact with industry-based clients and academic and clinical investigators, to support the design of and oversee the collation, management and integrity of clinical research data in collaboration with the Statistics team. The role will require the implementation of best practice research-based data management processes as determined by national and international clinical research management bodies and legislative requirements. The role will involve providing advice to clients and investigator on suitable approaches to data management, Case Report Form (CRF) development or amendment, creation and maintenance of documentation required to support database build, testing and release activities, data collection, validation, cleaning and quality control to ensure data quality and consistency.

See www.crfg.ie for more information on HRB-CRFG and for more information on Institute for Clinical trials www.universityofgalway.ie/instituteforclinicaltrials/

Salary: Research Associate/Postdoctoral Researcher salary scale €46,805 - €59,654 per annum, (subject to the project's funding limitations), and pro rata for shorter and/or part-time contracts.

The default position for all new public sector appointments is the 1st point of the salary scale. This may be reviewed, and consideration afforded to appointment at a higher point on the payscale (subject to the project's funding limitations), where evidence of prior years' equivalent experience is accepted in determining placement on the scale above point 1, subject to the maximum of the scale. (Research Salary Scales - University of Galway)

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Closing date for receipt of applications is 17:00 (Irish Time) on 30/05/2026. It will not be possible to consider applications received after the closing date.

Interviews are planned to be held approximately 2 weeks from application deadline.

***Please review full job description for further details and essential requirement.**

JOB DESCRIPTION

Job Description:
This post will require a thorough understanding of data management principles and best practices around data collection, quality control and preparation for analysis. The post will involve creation and management of a specific programme of research, meeting with and assessing the requirements of prospective clients and academic collaborators, contributing to the development of their research study's data management strategy and ensuring contractual obligations are met in accordance with agreed timelines. It would be an advantage to have an understanding of the entire clinical research process to anticipate and fulfil the clinical data needs of each study in accordance with FAIR Guiding Principles as they relate to data management. Developing the Data Management strategies will involve working closely with clinical and academic investigators, the respective study data management and biostatistics teams, to devise the data and/or analytic requirements based upon a research study proposal or trial protocol. The post-holder will provide professional management and co-ordination of clinical research data for individual trials. The post holder will require a thorough understanding of the entire clinical research process to anticipate and fulfil the data needs of each trial. This will involve working closely with the other members of the team including Principal Investigators to devise the data requirements based upon a clinical trial protocol and manage the creation of Case Report Forms. The role will involve CRF design and development, data collection, review and discrepancy management to identify errors and inconsistencies in CRF data and ensure their resolution in order to deliver a clean locked database for analysis, while ensuring adherence to relevant Standard Operating Procedures (SOPs) and ICH-Good Clinical Practice (GCP).

The successful candidate will contribute to the research and data management functions within the Data Management team, working with clinical staff and CRFG management to establish workloads, timelines and priorities.

Electronic Data Capture of clinical research data in the HRB-CRFG is an essential component of our clinical research activities, managed through a variety of electronic programs. A variety of clinical trial and registry development tools (Clinical Data Management Systems such as DFdiscover, Castor, REDCap etc) are utilised in the HRB-CRFG and proficiency in this area is an advantage. It is the responsibility of the Clinical Research Data Manager to plan for and resolve any issues that may occur during the capture of data in electronic format as well as ensuring that the data is high quality and delivered for analysis in an accurate and efficient fashion. The post holder will be expected to support funding submissions process by providing advice on Data Management aspects.

The post requires a thorough knowledge and understanding of the policy, practices and procedures relevant to the role, and provision of advice to junior colleagues on policy and standards relating to data management. The post holder will be expected to make a significant contribution to NUIG

research income by initiating, contributing to and/or supporting the development of research grant funding submissions by coordinating and providing guidance on data management, quality control processes, budgets and timelines.

Duties:

- Contribute to the design/review of the study protocol and provide input to the clinical trial team on data management issues.
- Design case report forms and ensure effective management of their generation and quality control.
- Prepare Case Report Form (CRF) completion instructions and present material for clinical trial activities at investigator meetings and site initiation visits.
- Train site personnel to help improve the quality of the data being collected.
- Assist with the development of training programs for Principal Investigators and research staff in data management.
- Define database requirements and data validations.
- Database testing
- Ensure ongoing data processing, generate and track all queries through to resolution.
- Develop reports to track study progress and measure data quality.
- Prepare clinical trial documentation including the data management plan.
- Ensure tasks documented in the study contract are completed on time, tracking task status to ensure smooth and successful timely locking of study databases.
- Update tracking systems and create/maintain Data Management Files (DMF) and appropriate study documentation.
- Ensure compliance with all ICH-GCP/EU/IRL regulations governing clinical trials.
- Assist in standardising data management procedures and data definitions within the department.
- Review, analyse, and validate clinical research data to ensure consistency, integrity and accuracy based on project specific guidelines in preparation for abstract submissions/publications
- Support CRFG research funding submission process by providing advice on Clinical Research Data Management aspects.
- Encode all clinical data in agreement with PI and statistician.
- Ensure appropriate and timely communications with investigative sites in the collection, entry, management, quality control and analysis of data, as required by investigators and sponsors.
- Ensure that Standard Operating Procedures (SOPs) are followed.
- Participate in system and vendor validations as required by the Data Management Group Lead
- Participate in audit as required within the department
- Undertake additional data activities as assigned by the Data Management Group Lead
- Any other duties assigned commensurate to this level of post

ELIGIBILITY REQUIREMENTS

Essential Requirements:

- University degree (Level 8) in a related field or equivalent professional qualification (minimum 5 Years)
- Minimum of 4 years' relevant work experience in a clinical research data management related role post primary degree
- Evidence of knowledge of clinical research, associated processes and regulations.
- Strong communication skills.
- Effective organisational skills and detail orientated.
- Highly motivated, with the ability to use initiative
- Strong team player with the ability to collaborate effectively
- Able to demonstrate a good and confident command of spoken & written English, sufficient to successfully discuss and explain complex technical ideas in simple & concise terms to a diverse range of stakeholders

Desirable Requirements:

- Experience working in a clinical research setting
- Experience in FAIR data management and application of Health Research Regulations 2018
- Experience working on EDC platforms such as DFdiscover, Castor, REDCap etc.
- Clinical or life science qualification
- An IT qualification

CONTINUING PROFESSIONAL DEVELOPMENT

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. University of Galway provides continuing professional development supports for all researchers seeking to build their own career pathways either within or beyond academia. Researchers are encouraged to engage with our Researcher Development Centre (RDC) upon commencing employment - see HERE for further information.

FURTHER INFORMATION/LINKS

- **TO APPLY:** Search Current University of Galway vacancies. Applications must be submitted online.
    - How to apply guide

- For informal enquiries, please contact Dr. Aideen O Doherty, Programme Manager, HRB-CRFG. crfg@universityofgalway.ie

- University's Strategic Plan

- Working in Research at University of Galway

- Moving to Ireland (Euraxess)
- Applicant Information
- We reserve the right to re-advertise or extend the closing date for this post.
- University of Galway is an equal opportunities employer.
- All positions are recruited in line with Open, Transparent, Merit (OTM) and Competency based recruitment.