OLLSCOIL NA GAILLIMHE
UNIVERSITY OF GALWAY

HR EXCELLENCE IN RESEARCH

Postdoctoral Researcher/Research Associate

Harmonised Approach to Early Feasibility Studies for Medical Devices in the European Union

School of Biological & Chemical Sciences, College of Science & Engineering

Ref. No. 011699

JOB ADVERTISEMENT

Applications are invited from suitably qualified candidates for a full-time, fixed term position as a Post-doctoral Researcher/Research Associate with the College of Science & Engineering at the University of Galway, Ireland.

This position is funded by the Innovative Health Initiative and is available from 31 May 2026 to contract end date of 30 September 2027.

1. The Project: HEU-EFS (Harmonised Approach to Early Feasibility Studies for Medical Devices in the European Union)

- **Project Overview:** HEU-EFS is a European Public-Private Partnership funded under the Innovative Health Initiative (IHI). The project's mission is to develop a standardized, harmonized framework to improve the uptake of Early Feasibility Studies (EFS) for medical devices across the EU. This aims to bring Europe in line with regions like the US, streamline the evidence-generation cycle, and accelerate patient access to innovative, safe, and effective medical technologies.
- **Consortium & Duration:** The project runs from October 2023 to September 2027. It is coordinated by Bocconi University and features 22 partners across Europe, including clinical sites, health technology assessment (HTA) bodies, patient organizations, and industry leaders.
- **Key Web Links & Bio Pages:**
  - **Official Project Website:** HEU-EFS Home
  - **European Commission CORDIS Profile (Grant Details):** HEU-EFS CORDIS Page
  - **Coordinator Bio/Project Page:** HEU-EFS at Cergas - Bocconi University

2. The Centre: School of Biological & Chemical Sciences (University of Galway)

College: College of Science & Engineering

Centre Overview: The College of Science & Engineering is a premier multidisciplinary school which contributes significantly to knowledge generation, technology development and translation, and to our economic and societal development. A major focus of the School is advancing fundamental and

applied sciences in areas such as therapeutics and biomedical science while actively supporting collaborations with MedTech and other sectors.

Key Facilities: The School leverages state-of-the-art laboratory infrastructure and core technological platforms across the University campus.

Key Web Links & Bio Pages:

Official School Website: College of Science & Engineering

Research Output & Investigator Profiles: School Research Portal

Associated Research Hub: Institute for Clinical Trials

Educational Programmes: Postgraduate Clinical Research Programmes

Salary: Postdoctoral Researcher/Research Associate 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)

Closing date for receipt of applications is 17:00 (Irish Time) on 3rd of April 2026. It will not be possible to consider applications received after the closing date.

Interviews are planned to be held on 17 April 2026

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

JOB DESCRIPTION

Job Description:
The successful candidate will play a key role in the HEU-EFS project, contributing to the development of a harmonized European framework for Early Feasibility Studies (EFS) of innovative medical devices. Working under the supervision of the Principal Investigator, the researcher will engage in regulatory and multi-stakeholder analysis to identify barriers to early-stage clinical investigations in the EU. They will assist in analysing regulatory frameworks, drafting manuscripts and educational materials, and collaborating with a consortium of clinical, regulatory, and industry partners to improve the evidence-generation lifecycle for medical technologies.

Duties:

- Research Execution: Plan, coordinate, and implement specific research activities related to the HEU-EFS work packages, including the analysis of regulatory barriers and the development of methodological frameworks for early-stage medical device testing.
- Methodology & Analysis: Determine and apply appropriate qualitative and quantitative research methodologies to support regulatory system analysis.
- Dissemination: Engage in the dissemination of research results under the supervision of the PI, including publishing regularly in high-quality peer-reviewed journals and presenting outcomes at international conferences and steering group meetings.
- Project Administration: Complete administrative work to support the research programme, including contributing to technical reports for the Innovative Health Initiative (IHI) and assisting in the financial management of project resources.
- Collaboration & Networking: Participate in internal and external networks to exchange information, build relationships for future research collaboration, and stay up to date with developments in the MedTech regulatory and clinical environment.
- Supervision & Mentoring: Mentor and assist graduate research students within the group and, where appropriate, contribute to limited teaching or tutoring (not exceeding 50 hours per annum) to support personal career development.
- Compliance & Standards: Maintain a thorough knowledge of university policies and legal requirements, specifically regarding Research Ethics, Data Protection/GDPR, and Intellectual Property Rights relevant to medical device data.
- Professional Development: Actively engage in appropriate training and professional development opportunities to acquire generic and transferable skills and build an independent research reputation.
- Any other duties assigned commensurate to this level of post

ELIGIBILITY REQUIREMENTS

Essential Requirements:

- Education: A PhD in a relevant discipline (e.g., Biomedical Engineering, Biomedical Science, Regulatory Science, Law/Ethics in Technology, or Clinical Research).
- Note: Candidates who have submitted their thesis and are awaiting VIVA may be considered and, if successful, will be appointed as a Research Associate (Point 1 of scale) until the PhD is awarded.
- Research Experience: Evidence of a minimum of 2 years of research experience in the field of medical devices, clinical trials, or regulatory affairs.
- Technical Knowledge: A demonstrable understanding of the European Medical Device Regulation (MDR 2017/745) or the lifecycle of early-stage medical technology development.
- Dissemination Track Record: Evidence of a track record of high-quality publications in peer-reviewed journals and/or presentations at relevant international conferences, commensurate with the stage of their career.
- Communication Skills: Excellent writing and communication skills, with the ability to synthesize complex regulatory or technical information into clear reports for diverse stakeholders.

Desirable Requirements:

- Stakeholder Engagement: Previous experience working within international or EU-funded consortia (e.g., Horizon Europe, IHI, H2020) and engaging with multi-disciplinary partners.
- Methodological Expertise: Familiarity with qualitative research methods (e.g., semi-structured interviews, Delphi studies) or research of the medical device regulatory framework.
- Project Management: Demonstrated ability to manage project deliverables, meet strict deadlines, and contribute to the preparation of research grant applications or technical reports.
- Networking: Experience in liaising with regulatory bodies (such as Notified Bodies or National Competent Authorities) or clinical investigators involved in Early Feasibility Studies.

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 Tom Melvin, Associate Professor in Medical Device Regulatory Science, Email tom.melvin@universityofgalway.ie or Olivia McDermott, Associate Professor in Regulatory Affairs and Operational Excellence at the University of Galway olivia.mcdermott@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.

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- University of Galway is an equal opportunities employer.
- All positions are recruited in line with Open, Transparent, Merit (OTM) and Competency based recruitment.