JOB DESCRIPTION RE CLINICAL INDUSTRY LIAISON OFFICER ROLE

<table>
<thead>
<tr>
<th>Post Title:</th>
<th>Clinical Industry Liaison Officer, CILO, Health Research Board Clinical Research Coordination Ireland</th>
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<tbody>
<tr>
<td>Post Status:</td>
<td>Fixed contract until 30 April 2018, with possible extension</td>
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<tr>
<td>Organisation:</td>
<td>Molecular Medicine Ireland</td>
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<tr>
<td>Location:</td>
<td>Molecular Medicine Ireland, 28 Upper Mount Street, Dublin 2</td>
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<td>Reports to:</td>
<td>Chief Operations Officer, HRB CRCI</td>
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<td>Salary:</td>
<td>Negotiable</td>
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<tr>
<td>Closing Date:</td>
<td>5:00 pm, Monday 11 September 2017</td>
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<tr>
<td>Application Process:</td>
<td>Curriculum Vitae and covering letter containing names of 3 referees to be sent for the attention of Dr Fionnuala Keane to <a href="mailto:info@molecularmedicineireland.ie">info@molecularmedicineireland.ie</a></td>
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HRB CRCI Background

With the support of Health Research Board, Enterprise Ireland and Molecular Medicine Ireland, the five University-based Clinical Research Facilities/Centres (CRFs/Cs) in the Republic of Ireland have developed an integrated clinical trials network, the Health Research Board Clinical Research Co-ordination Ireland (HRB CRCI).

The aim of the HRB CRCI is to enhance Ireland’s capacity for conducting innovative high quality clinical research for the benefit of people’s health and the economy. It will advance the care of patients by enabling a connected and coordinated Clinical Trial Network. This network provides the skills, expertise and infrastructure to design, conduct and analyse multi-centre clinical trials involving human participants in Ireland. It supports both academic or industry initiated clinical trials involving pharmaceuticals, nutriceuticals or clinical care pathways as well as clinical investigation of medical devices.

The HRB CRCI wishes to appoint a Clinical Industry Liaison Officer on a fixed term contract until 30 April 2018, with the possibility of extension. The successful candidate will be responsible for the development of clinical research process knowledge and awareness among researchers, high potential start-up (HPSU), pre-start-up, bio-pharmaceuticals, nutriceutical, diagnostic and multinational life-science companies.

The Clinical Industry Liaison Officer position will be funded by Enterprise Ireland and will be based within the central office of the HRB CRCI at Molecular Medicine Ireland with the expectation of national travel. The Clinical Industry Liaison Officer will report to the HRB CRCI Chief Operating Officer and the employment and HR policies of Molecular Medicine Ireland will apply.

RESPONSIBILITIES

1. Company Engagement
   • Build on existing relationships but also focus on new relationships between
established, high potential start-up (HPSU), pre-start-up, researchers, bio-pharmaceuticals, diagnostic and multinational (max 10% of CILO time) life-science companies and the clinical community to help address clinical research needs with a primary focus on the medical device industry

- Target of 70 (per annum) contacts/companies, to include companies where relationships are already established. Priorities and target companies to be agreed/reviewed at start of new contract and at annual meetings thereafter between Enterprise Ireland and HRB CRCI.
- Work in-depth with 8-12 (per annum) key Enterprise Ireland client companies to help address their clinical research needs so that they can engage in clinical trials.
- Establish new relationships with key academic spin-outs and established companies (as agreed with Enterprise Ireland) to help them address their clinical research needs e.g. pre-clinical research requirements, clinical investigation documentation, and identification of relevant clinical and relevant support services required.
- Work closely with Development Advisors/ Commercialist Specialists in Enterprise Ireland to identify the supports required by Enterprise Ireland client companies during their development process from concept to commercialisation.

2. Information Services

- Develop resources on the HRB CRCI web portal to assist Enterprise Ireland client companies and late-stage clinical researchers (in the areas of medical devices, diagnostics and pharmaceuticals) on clinical trial processes, clinical research legislation, regulatory and ethical requirements for all phases of clinical development from proof of concept to commercialisation.
- Identify the supports and training required to ensure the implementation of new legislation and consultations as they are published, primarily in relation to the med-tech industry.
- With regard to the above, provide In-house training to HRB CRCI staff, working with the Quality and Regulatory Affairs Manager.

3. Training & Outreach

- Contribute to HRB CRCI training activities nationally e.g. Medical Devices, GCP, Clinical Development, Monitoring, Risk Management Quality Systems Management and Health Technology Assessment
- Provide training & workshops to Enterprise Ireland client companies, academics and other companies as required, working with the HRB CRCI Quality and Regulatory Affairs Manager on course content where necessary.
- Promote Ireland as a location for clinical trials/investigations for medical devices, diagnostics and pharmaceuticals. Identify gaps in order to deliver international quality standards systems to support the medical device, diagnostic and pharmaceutical industry.

4. Policy & Benchmarking

- Provide strategic information to Enterprise Ireland and help input into policy initiatives, as determined by EI.
- Benchmark Ireland’s clinical research infrastructure with other countries, particularly with regard to the med-tech industry, through market research and site visits.

5. Auditing and Monitoring

- Assist the Quality and Regulatory Affairs Manager and Lead Clinical Trial Liaison Officer with clinical study auditing and monitoring when required.
6. Other
• Assist HRB CRCI to identify investigators to participate in clinical studies.
• Assist and input into the development of progress and grant reports for HRB CRCI.
• Support the HRB CRCI ECRIN-ERIC observer role.

REQUIREMENTS

• Degree level qualification in a clinical or life sciences related subject.
• Extensive experience within a commercial/academic clinical research environment.
• A high level of understanding of the current Irish medical, academic and health services research environment.
• Thorough knowledge of the regulatory approval processes for pharmaceutical, diagnostic and medical device companies in Europe and the USA.
• Extensive project management with excellent organisational and IT skills.
• Strong leadership and communication skills (oral, written & presentation).
• Self-motivated and able to work independently, showing initiative and good judgment.

MMI will put in place an appropriate training plan to support the Clinical Industry Liaison Officer in the delivery of grant objectives over the term, enabling the Clinical Industry Liaison Officer role to carry out its primary duties.

Molecular Medicine Ireland is an equal opportunities employer