

Luxembourg Institute of Health is a public research organisation at the forefront of biomedical sciences. With its strong expertise in population health, oncology, infection and immunity as well as storage and handling of biological samples, its research activities impact on people's health. At the Luxembourg Institute of Health, devoted scientists investigate disease mechanisms to develop new diagnostics, innovative therapies and effective tools to implement personalised medicine. The institution is the first supplier of public health information in Luxembourg, a strong cooperation partner in local and international projects and an attractive training place for ambitious early-stage researchers.

## Clinical Research Associate

2-year fixed-term contract, full time, Start date: ASAP

The Clinical Research Associate work at LIH's Clinical and Epidemiological Investigation Center. She/He will:

- Coordinate clinical research projects according to the protocol, budget and fixed timelines.
- Supervise and assist regulatory submissions to health authorities including the national research ethics committee.
- Support private sponsors, researchers and investigators from other research institutions or hospitals in the set up and conduct of clinical research projects.
- Ensure compliance with the applicable legal, administrative and regulatory requirements.
- Provide specific expertise and know-how in clinical research.
- Provide support to safety reporting and adverse events reporting.
- Monitor clinical trials and guarantee the quality of the scientific data collected during the study.

### Key Accountabilities

- Be the interface between the various partners involved in clinical research projects including clinicians and researchers.
- Conduct the regulatory submissions according to the applicable laws and obtain approvals.
- Set-up financial contracts and manage financial aspects during the projects.
- Monitor and coordinate clinical research activities at different sites both at a national and international level including study design activities, initiation with all involved partners, monitoring, safety reporting and data management.
- Collect data, report it in the CRF and check that the data entered is consistent with the medical record of each patient.
- Participate in the quality procedure (evaluation process, drafting procedures, etc.), implementation of SOPs (Standard Operating Procedures) and their validation process.
- Participate in European consortia and grant applications.
- Ensure on-site monitoring of clinical research projects at different sites, both nationally and internationally.

### Key Skills, Experience and Qualifications

- Master's degree in the field of Medical/Health, Biomedical, or Life Sciences or Biology/Biotechnology related sciences.
- Certified clinical research training (DIU-FARC, DIU-TEC, etc.).
- At least 2 years of experience in the domain of clinical research (CRO, clinical trial unit or research centre, pharmaceutical industry) including a significant on-site monitoring experience.
- Experience in multi-center international clinical trials.
- In-depth knowledge of the clinical research working rules in Luxembourg/Belgium and Europe (legal context, patient rights, data protection, etc.) and the international directives (International Conference on Harmonization - Good Clinical Practice: ICH-GCP) as well as the Clinical trials - Directive 2001/20/EC repealed by the Clinical Trials Regulation.
- Knowledge of regulatory requirements for clinical trials.
- Ability to interact positively with advisors and regulatory authorities.
- Independent and multidisciplinary team working abilities, meticulous, motivated, creative and scientifically innovative.
- Strong oral and written communication skills, be able of summarising ideas and prioritising.
- Language skills: Fluent in French and English. Any other commonly spoken language in Luxembourg such as Portuguese, German or Luxembourgish would be an added advantage.

Located in Luxembourg, LIH offers the opportunity to work in a dynamic, international and multilingual environment that values personal respect and professional achievement based on the highest intellectual and ethical standards. The remuneration for this position shall be based on qualification and experience.

**Applications including cover letter and a CV should be sent before August 24, 2020 through our website [www.lih.lu/jobs](http://www.lih.lu/jobs) with the ref : CM/CRA0720/MA/CIEC**