Reference: 027-22

JOB OFFER

Lleida Biomedical Research Institute is recruiting a:

- Clinical trial monitor -

The Institute

The IRBLleida aims to promote, develop, transfer, manage and disseminate research excellence, scientific and technological knowledge, teaching and training in the field of life sciences and health. To this end, it promotes relations and the exchange of knowledge between the research staff and research groups belonging to the various centres and entities in the biomedical field, which operate mainly in the Lleida area; it promotes collaboration with other institutions and entities, prioritising the implementation of joint projects; it raises funds to finance research activities of excellence of interest to the aforementioned centres and devices; and it manages the research resources entrusted to it by the various institutions and entities that form part of it. Within the territorial environment, it collaborates closely with:

- The University of Lleida (UdL) includes researchers from the Faculties of Medicine and Nursing and Physiotherapy.
- The Catalan Healthcare system includes healthcare staff from:

  o Catalan Health Institute (ICS): Arnau de Vilanova University Hospital (HUAV), the Lleida Primary Care and Community and Primary Care in the Alt Pirineu-Aran Health Region

  o Gestió de Serveis Sanitaris (GSS): Santa María University Hospital (HUSM), Pallars Regional Hospital and Mental Health, among others.

The IRBLleida is a CERCA institute with its own legal status: Fundació Institució dels Centres de Recerca de Catalunya (I-CERCA) de Catalunya, which is organised according to a model of good governance and operation that ensures efficiency, management flexibility, recruitment and promotion of talent, strategic planning and executive capacity. It is also a Health Research Institute (IIS) accredited by the Carlos III Health Institute and the Government of the Generalitat, as established by Law 16/2003, of 28 May, on the cohesion and quality of the national health system.

In December 2014, the Lleida Biomedical Research Institute's received the 'HR Excellence in Research' logo from the European Commission. This is a recognition of the Institute's commitment to developing an HR Strategy for Researchers, designed to bring the practices and procedures in line with the principles of the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers (Charter and Code).

Please, check out our Recruitment Policy

Professional profile:

- Research Technician.

HR EXCELLENCE IN RESEARCH

Requirements and characteristics to be met:

- Degree in Health Sciences
- Master's Degree in Clinical Trial Monitoring
- Current Good Clinical Practice Certificate

Functions:

The selected person will join the Biomedical Research Institute of Lleida (IRBLleida) to fill a post of Clinical Trial Monitor in the Clinical Trials Unit (UAC), corresponding to those provided for in DA 6.ª of Law 20/2021, of 28 December, on urgent measures for the reduction of temporary employment in public employment. This law authorises the call for the stabilisation, on an exceptional basis and in accordance with the provisions of article 61.6 and 7 of the TREBEP, by means of the competition system, of those positions which, meeting the requirements established in article 2.1, had been occupied on an uninterrupted temporary basis prior to 1 January 2016.

The stabilisation of this post was approved in the Agreement of the IRBLleida Board of Trustees on 3 June 2022.

The selected person will assume the tasks of monitor and CTA in the active studies of the SCTFARMA Service during the duration of the contract with the mission of collaborating in the supervision of the progress of the clinical trials of the SCTFARMA service in order to contribute to the fact that they are performed, registered and reported to the Regulatory Agencies following the trial protocol, the defined Good Clinical Practices (GCPs) and the current legislation.

The areas of responsibility and functions of the job position are, among others, the following:

- Collaborate in the choice of the center and the investigator team, including their training, to contribute to the fact that the trial protocol, Good Clinical Practices and current legislation are followed at all times.
- To verify the veracity of the data collected from the clinical trial participants and the traceability of the medication used during the trial, in order to facilitate that the rights and welfare of the participating subjects are protected at all times and that the procedures are in accordance with the approved protocol.

- Provide clinical trial related billing to sponsors to provide benefits to the clinical trial pharmacy service (SCTFarma).
- Complete and keep up to date all information regarding the clinical trial in order to archive it according to the current regulations.
- Maintain contact with the research team, the sponsor and the regulatory agencies to ensure that the evolution of the trial and its possible adverse effects are communicated in accordance with current regulations.
- To collaborate in those technical or administrative tasks, if necessary, that are entrusted to him/her by his/her responsible, management or direction, with the purpose of contributing to the achievement of the objectives of his/her area or department of the IRBLleida.
- Participate in the Committees and Commissions that the place requires, with the purpose of ensuring the achievement of the objectives of IRBLleida, complying with the legislation in force according to the matter in which he/she participates.

Desirable but not required/ Nice to have

- Experience as CRA and CTA of clinical research (internal medicine, neurology).
- Training in CTIS platform
- Knowledge of patient management software: Fundanet and SAP
- Proficiency in EudraCT and ECM Portal platforms
- Knowledge of scientific and clinical English (with qualifications)
- Ability to organize and multitask
- Ability to work as part of a team and to respect the organizational chart
- Creativity, empathy and enthusiasm
- Ease of learning

The Offer – Working Conditions

- Type of contract: Indefinite
- Planned start date: Immediate
- Workday: Full time 37.5 hours per week
- Remuneration: 21.000 euros gross / year

We provide a highly stimulating environment with state-of-the-art infrastructures. To check out our training and development portfolio, please visit our website in the training section.

We offer and promote a diverse and inclusive environment and welcomes applicants regardless of age, disability, gender, nationality, race, religion or sexual orientation.

The IRBLleida is committed to reconcile a work and family life of its employees and are offering the possibility to benefit from flexible working hours.

Documents and application deadline:

All applications must include:

- A motivation letter
- A complete CV including contact details and National Identity Document number

Deadline: Please submit your application by July 05, 2022. Latest time for the submission of applications: 14:00 h - Europe/Brussels

Those interested can apply to the 027-22 offer by filling out the form available at https://www.irblleida.org/ca/job-application/ and attaching a CV and a cover letter.

Selection process schedule for reference 027-22	
15 days	Publication and dissemination of the job offer: IRBLleida website, social networks, other employment websites according to the features of the job offered
Next 2 working days	Transfer of the CVs to the Selection Committee
Next 5 working days	Meeting of the Selection Committee: - Interview of the pre-selected candidates - Evaluation of the candidates and meeting minutes certifying the candidate awarded with the position - Communication of the selected candidate to HR

Next 5 working days	Completion of the paperwork required to formalize the employment contract
Immediate	Approximate contract starting date

Express selection process

When an employee must be replaced urgently, for instance, to cover a sick leave, scientific reasons justifying the incorporation on a specific day, specification in a resolution, etc., an express selection process could be undertaken.
This selection process will follow the same procedure as the ordinary one, but the duration of several steps will be reduced, *i.e.* publication of the job offer, submission of applications, evaluation and selection process.

The contract will be in accordance with the provisions of **article 15 of Royal Legislative Decree 1/1995, of 24 March**, approving the text of the Workers' Statute Act, in accordance with the provisions of **article 2 of Royal Decree 2720/98, of 18 December (B.O.E. of 8 January 1999), Law 12/2001, of 9 July (B.O.E. of 10 July)** and concordant provisions.

The principle of equality between men and women is taken into account, in accordance with **Organic Law 3/2007, of 22 March**, for the effective equality of women and men.

The principle to equal opportunities and treatment, as well as the real and effective exercise of rights by people with disabilities on equal terms with other citizens, through the promotion of personal autonomy, universal accessibility, access to employment, inclusion in the community and independent living and the eradication of any form of discrimination, in accordance with **articles 9.2, 10, 14 and 49 of the Spanish Constitution** and the International Convention on the Rights of Persons with Disabilities and the international treaties and agreements ratified by Spain, in accordance with the provisions of **Royal Legislative Decree 1/2013, of 29 November**.

Informative clause for the processing of personal data

Responsible: Institut de Recerca Biomèdica de Lleida Fundació Dr. Pifarré
Purpose: Management of job offers.
Legitimation: The legal basis of the treatment is the completion of a selection process to fill a position.
Recipients: The data will not be transferred to third parties, except in the legal obligations set by law.
Rights: Access, rectification and deletion of data, as well as other rights, as explained in the additional information.
Additional information: Additional and detailed information on Data Protection can be found our website http://www.irblleida.org/en/legal-notice/

IRBLleida is committed to the principles of merit-based recruitment and transparency (OTM-R) in accordance with the HRS4R seal requirements.

ANNEX I: SELECTION COMMITTEE

PRESIDENT

- Institut de Recerca Biomèdica de Lleida Principal Investigator
  - Dr. Diego Arango del Corro

CHAIRS

- Researcher IRBLleida
  - Dr. Schoenenberger

- Head of the SCTFarma at IRBLleida
  - Mrs. Laura Rumi

SECRETARY

- IRBLleida HR manager
  - Mrs. Elena Moscatel Mendelsohn

ANNEX III: SCALE OF MERITS

a) Academic curriculum and complementary training - 30 points.

Valued:

- CTIS Training — 20 points
- Justifiable academic background in English — 10 points

b) Certified professional experience - 50 points

- Demonstrable experience in the monitoring of independent and external laboratory assays — 20 points
- Demonstrable experience as a CTA in the submission of trials to regulatory agencies (EudraCT platform and ECM Portal) — 20 points
- Demonstrable experience in patient management programs: SAP, Fundanet — 10 points

c) Competence test or interview – 20 points

Criteria subject to a value judgement will be assessed on the basis of

Applications that do not exceed 50% of the maximum score will be rejected.