

INTERNAL CALL

The Institute

The **Santa Creu i Sant Pau Hospital Research Institute Foundation** is a scientific foundation which mission is to improve health and quality of life of the population, through the production and dissemination of scientific knowledge, training of researchers to an international standard, and promoting health innovation and the incorporation of medical advances in clinical practice and healthcare policies. Created in 1992, the institute was attached to the Autonomous University of Barcelona (UAB) in 2003, and since 2011 it is part of the Government of Catalonia's CERCA Programme.

For the Foundation, it is a priority to ensure that the most suitable candidate is hired to fill a job through an open, transparent and merit-based selection process (OTM-R). Following these guidelines, staff mobility, knowledge exchange and, ultimately, the increase in the quality of teaching and research will be enhanced. Faithful to our commitment to the European Union's human resources strategy, our institution's personnel selection and recruitment procedures are governed by a set of basic principles that guarantee equal access to employability for all. Therefore, the constitutional principles of equality, merit and ability are followed, respecting in all cases the national and international regulations in force in this area, specifically the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers (C&C). The principles of C&C are applicable to the recruitment of any personnel of the institution, regardless of their professional category. For this reason, our Foundation has obtained the recognition of "Excellence in R+D in Research" granted to the IIB Sant Pau, since 2015.



The **Santa Creu i Sant Pau Hospital Research Institute Foundation** needs to incorporate at the **Clinical Research and Clinical Trials Unit (UICEC)**:

AC4- Clinical Monitor (CRA)

About the Unit:

The Clinical Research and Clinical Trials Unit (UICEC Sant Pau) offers extensive support to researchers in the development of independent research projects (not sponsored by the pharmaceutical industry) on methodology, regulation, administrative, economic and practical aspects, subjects in compliance with legislation and Good Ethical Clinical Practices.

The UICEC Sant Pau is part of the Spanish Clinical Research Network (SCReN), a functional organization network to support the conduct of multicenter clinical trials and participates in the SCReN Platform (Spanish Clinical Research Network ISCIII).

Knowledge management:

- Single window of information for independent research group projects.
- Comprehensive advice and project coordination.
- Communication point between researchers and technical units.
- Pharmacovigilance activities for clinical trials that include medications or health products.
- Dimensionality and feasibility studies of projects.
- Identification of the needs of each project.
- Advice on the preparation of documentation: protocol, annexes, monitoring report, final report.
- Advice on the presentation of documentation to the Spanish Agency for Medicines and Health Products (AEMPS) and other competent authorities.
- Advice on registering projects in public databases.
- Identification of Spinoff projects.
- Advice on the presentation of research results.

Methodological and statistical support:

- Advice on study design. - Data entry.
- Data processing.
- Preparation of statistical reports.
- Validation and management of electronic CRFs.
- Documentation and reports.

Documentation, filing, control and monitoring:

- Support in the creation of documents: EudraCT form and annexes / application forms / evaluation and monitoring forms.
- Support in the processing of initial requests, clarifications and modifications: AEMPS, CEIC, other health authorities regarding clinical trials and other post-authorization studies.
- Comprehensive monitoring of clinical trials and observational studies.
- Management of initial, follow-up and final reports.
- Development and custody of files (Master File), preparation of the investigative file.
- Other communications to the CEIC, CCAA and competent authorities.

Financial management and direction:

- Management of clinical trial contracts with participating centers.
 - Management of collaboration agreements with laboratories / companies for financing.
 - Management of contracts related to clinical trials (CRO's, E-CRDs, statistics, etc.).
- Management of customer and supplier invoices.
- Management of clinical trial insurance policies.
 - Preparation of financial reports for the presentation of studies to ethics committees.
 - Management of payment of fees to the competent authorities.

Essential requirements

- Minimum qualification required: Higher Education (Bachelor's Degree, University Degree) in Health Sciences.
- Specific training in Clinical Trials (Master's degree in Clinical Trial Monitoring)
- Training in Good Clinical Practice and Quality standards.
- Minimum 2 years of accredited professional experience.
- Oral and written knowledge of the two official languages of Catalonia or, failing that, the successful candidate will have to demonstrate, or promise to obtain, within a period not exceeding one year, a correct knowledge of the two official languages of Catalonia.
- Intermediate Level of English.
- Advanced knowledge of office tools (excel, word, power point, etc).

Skills will be valued

- Professional experience in tertiary hospitals.
- Professional experience in managing independent clinical trials.
- Experience in managing clinical trials with the ISCIH SCREN.

Functions

- Monitoring activities of the clinical research project.
- Monitoring of clinical trials.
- Assistance in the development of clinical trials and other studies.
- Acting as a communication channel between the promoter (FIRHSCSP) and the research staff.
- Advice on current legislation regarding clinical trials and other biomedical research projects.

Offered

- Indefinite contract.
- Annual workday of 1.627,50 hours (37,5 hours/week).
- Remuneration according collective agreement.
- Research Group: Clinical Research and Clinical Trials Unit (UICEC).

Documentation and deadline for submission

Interested parties should preferably deliver the documentation (1) in PDF, by e-mail to the Management of the Santa Creu i Sant Pau Hospital Research Institute Foundation, address ir_seleccio@santpau.cat, indicating the reference **2023/218**:

(1) Application letter and updated Curriculum Vitae

At the request of the Santa Creu i Sant Pau Hospital Research Institute Foundation, the candidates must present the documentation accrediting the merits mentioned in the curriculum vitae.

Applications will be resolved within a maximum period of one month from the end of the deadline for submission of documentation. At the end of this period, without having been notified of an express resolution, the interested parties will be entitled to understand that their applications have been rejected.

Santa Creu i Sant Pau Hospital Research Institute Foundation may declare this call for applications closed if, according to its criteria, the candidates does not meet the conditions that the Institution considers necessary to fill the position.

The interpretation of the requirements and their enforceability to the candidates will be exclusive to the Santa Creu i Sant Pau Hospital Research Institute Foundation.

**The deadline for submitting applications
will end on November 13th 2023, at 3:00 p.m.**

****The promotion will be effective retroactively from October 1th, 2023**

Fundació Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau, sited at C. Sant Quintí, 77-79, 08041, Barcelona, Tel: 93 291 90 50, NIF: G-60136934, as Data Controller and in compliance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) and the Organic Law 3/2018 of 5th of December, on the protection of personal data and the guarantee of digital rights, will treat your data with the sole purpose of developing this call. The legal basis for this treatment is the article 6.1 a, c and f from the GDPR, giving that we will ask for your consent, the treatment is necessary for the application of precontractual measures and its necessary to satisfy the legitimate interests pursued by the Data Controller.

The data will be kept during the necessary time to develop the call. Data will be treated solely by that areas and services that are allowed to in accordance with their assigned competences and functions. There will be no data cessions made unless there is a legal obligation to do so. You are entitled to exercise the rights of access, rectification, deletion, opposition, limitation and portability. In case you have any doubts, you can contact the data protection delegate at dpo_ir@santpau.cat. You also have the right to file a complaint to the relevant control authority.

PERMANENCE COMMITMENT: *Selected persons who will hold the summoned or vacant position, will not be able to apply for a new call until 1-year period has expired. In case of part-time job positions, this period will be of 6 months. In both cases, the period will compute from the date of publication of the resolution. The vacant summoned, and the ones that derive from it (intern movements), will be successively covered on the same proceeding among the submitted candidates to each particular call, regardless of whether this entails coverage of places in turns other than the call.*

Barcelona, 30/10/2023



Human Resources Departament
Santa Creu i Sant Pau Hospital Research Institute Foundation