

## JOB OPPORTUNITY

Open Call on competitive basis at the **FUNDACIÓN PARA LA INVESTIGACION BIOMÉDICA DEL HOSPITAL CLÍNICO SAN CARLOS-IdISSC** for a position as **Lead Clinical Research Associate** at the Cardiology Unit, for the following project funded by Horizon 2020 Work Programme: "SECURE".

Full-time contract (37.5 hours per working week).

The starting date will be immediately after call closure and the duration of the contract will until 31st December 2021 approximately or when funds allocated to this project are completely expended or the end of the project. Gross salary per month will be 1833€ or 2125€ approximately according to candidate value, in accordance with Spanish Law.

### JOB DESCRIPTION/RESPONSABILITIES

- To monitor the activities of the clinical research project conducted in the assigned sites.
- To ensure effective communication between the research team and the sponsor in the sites to which they are assigned.
- Under the coordination of the Project Manager, to participate in the selection of the sites: To determine the suitability of the facilities, staff, access to suitable patients and participation in competitive projects.
- To make the initial visit and train the research team in the project activities.
- To monitor in compliance with the Monitoring Plan and Manual.
- To verify compliance with the protocol and its modifications.
- To ensure compliance with the Good Clinical Practices, the applicable current legislation and the Standard Operating Procedures.
- To perform the close-out visit of the clinical research project.
- To prepare the Monitoring Reports and the review in a timely manner for the project manager/sponsor.
- To maintain the essential documentation of the project updated and correctly filed in the Master File of the project in the assigned sites.
- To assist in the resolution of inconsistencies, deviations and errors in the trial data –queries -
- To ensure the traceability of the medicinal product delivered to the assigned sites and to manage any incidence
- To maintain the information required from the assigned sites in the project tracking tools - CTMS and SCReN Intranet -
- To actively collaborate in assuring the quality of the assigned site data, documentation and processes
- To assist the Project Manager in the activities prior to an internal or external audit or inspection and to assist in the development of the same.
- To assist the Pharmacovigilance Manager and/or the Project Manager in the follow-up of the reported SUSARs, SAEs, SARs or AEs.
- Under the coordination of the Project Manager, to review eCRD data and documentation for all clinical trial sites.
- Under the coordination of the Project Manager, to participate in the close-out activities of the project.

### EDUCATION AND TRAINING REQUIREMENTS

- University degree in Health Sciences.
- Educational background in Clinical Trials Monitoring.

### HOW TO APPLY

Application deadlines: **18<sup>th</sup> December 2020 until 10<sup>th</sup> January 2021**.

Applicants should send their CV through our application form located in our website (<http://www.idissc.org/unete-a-nosotros.php>), clearly quoting the Reference: "**GES-31-2020**".

When applying, applicants will accept total compliance with the job offer and will be fully responsible for the accuracy of the information submitted. The applicants must provide the following related documents (if they are requested by the FUNDACIÓN): National Identification Number/Passport; original and/or certified copy of University Degree or any other merit mentioned.

### SELECTION CRITERIA

The applications will be evaluated by a designated Evaluation Committee (only if they meet the Education and Training Requirements). This Committee will act in accordance to the following criteria:

#### A) Merit expertise:

1. Monitoring experience/trainee in Clinical Trials (it will be valued : 0-4)
2. Regulatory activities; MoH and EC submissions, eCM, REec, EudraCT management (it will be valued 0-1)
3. Previous experience/trainee in Clinical Trials within Public Health System; GCP knowledge (it will be valued 0-2)
4. Computer skills (it will be valued 0-1)
5. Mobility and English: fluent. (it will be valued 0-2)

**B) Job Interview (only if you overcome 5 points at A) Merit Expertise).** Previous labour mobility and personal experience, including the experience obtained in non-standard or informal ways, will be assessed. (0 to 5 points)

The official resolution will be published the day after the process is finished. Any claim could be submitted to the designated Selection Committee the next five days after the resolution is published.

Date: **18<sup>th</sup> December 2020**