JOB OPPORTUNITY

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

Full-time contract (37.5 hours working week).

The starting date will be immediately after call closure and the duration of the contract will until 30th April 2020 approximately or when funds allocated to this project are completely expended or the end of the project. Gross salary per month is 2.145€ approximately, in accordance with Spanish Law.

JOB DESCRIPTION/RESPONSABILITIES

The Project Manager is responsible for leading and coordinating the clinical research projects, ensuring that they are properly developed in all their stages, from the initial study planning to the close-out of the study activities, according to the procedures that are established in the study protocol and the monitoring plan, and in compliance with Good Clinical Practices and current legislation:

- To act as the main contact of the sponsor throughout the project, if so designated.
- To assist in selecting and evaluating the sites to participate in the project.
- To establish a specific Monitoring Plan and Manual for each project and to monitor the same to ensure compliance.
- To work with the project sponsor to ensure that it is completed in accordance with the budget plan, deadlines and commitments established by SCReN.
- To coordinate, together with the Principal Investigator, the study's practical development, and to establish the necessary communication channels between all the agents involved in the project until the close-out of the sites.
- To supervise the establishment and maintenance of essential trial documentation, updated and properly filed in the project Master File.
- To coordinate all the regulatory documents of the research project.
- To conduct all the regulatory activities at national level (local EC, CEIm, AEMPS) Site contracts management.
- To train, supervise and assist the CRA team.
- To supervise the monitoring activities carried out by CRAs.
- To conduct co-monitoring visits, if required.
- To review and approve the reports of the site visits
- To coordinate the proper control of the project's investigational product.
- To coordinate or collaborate in the project's safety surveillance - pharmacovigilance.
- To coordinate or collaborate in data collection and management to evaluate the project's effectiveness and safety.
- To collaborate in the proper design of the Case Report Form, in paper or electronic format.
- To coordinate or collaborate in drafting the regulatory or project management intermediate reports.
- To keep the information updated in the project Management tools - CTMS and Intranet SCReN -.
- To coordinate or collaborate in preparing the project's Final Report.
- To maintain a detailed analysis of risk and quality.
- To coordinate, together with the Principal Investigator and the sponsor, 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.

EDUCATION AND TRAINING REQUIREMENTS

- University degree in health sciences.
- High level of English.

HOW TO APPLY

Application deadlines: **09th August 2019 until 01st September 2019.**

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: **"CIC-7-2019"**.

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. At least 3 year CRA experience (0 a 3 points)
- 2.Previous experience in Management of Clinical Trials (0 a 3 points)
- 3. Previous experience in regulatory activities and clinical site selection, training and management (0 a 3 points)
- 4. Mobility (0 a 1 points)

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: 09th August 2019

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