

JOB OPPORTUNITY

AMENDMENT TO THE JOB OPPORTUNITY PUBLISHED ON 2ND JULY 2019:

Open Call on competitive basis at the **FUNDACIÓN PARA LA INVESTIGACION BIOMÉDICA DEL HOSPITAL CLÍNICO SAN CARLOS- IdISSC** for a position as Clinical Trials Monitor at the Rheumatology Unit, for the following project funded by EIT HEALTH Programme Call 2019- Innovation by Ideas (non-focus area): PRediction mEdical Devlce for Rheumatoid Arthritis: PREDIRA
Where it says: Full-time contract (37.5 hours per working week). Must it says: Part-time contract (36 hours per working week)
The starting date will be immediately after call closure and the duration of the contract will be 18 months approximately or when funds allocated to this project are completely expended. **Where it says: Gross salary per month is 1551€ approximately. Must it says: 1489,10€**, in accordance with Spanish Law.

JOB DESCRIPTION/RESPONSABILITIES

The monitor acts as the main connection between the investigators and the manager or the sponsor, for everything related to the monitoring and supervision of the Project activities carried out in the assigned research sites, ensuring compliance with the Good Clinical Practices, the applicable current legislation, the protocol and its approved amendments and the Standard Operating Procedures. He/she maintains regular contacts with the investigators of the assigned sites.

- To prepare, present and follow up the documentation directed to the mRECs and Regulatory Authorities, from project start-up to completion.
- To process the contracts and liaise between the project sponsor and the sites.
- To prepare and maintain the Master File, the Investigator's File and the project's essential documentation.
- To liaise with the research team, institutions and other participants in the project.
- To create and maintain the project records: Amendment records, version control of essential documentation, etc.
- To prepare, manage and distribute the project materials. To maintain and register the project materials.
- To monitor the activities of the clinical research project conducted in the assigned sites.
- 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 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 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.

EDUCATION AND TRAINING REQUIREMENTS

- University degree or equivalent in health sciences.
- Master of Clinical Trials Monitor (completed).

HOW TO APPLY

Application deadlines: **2nd July 2019 until 07th July 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: "**TEC-8-2019**".

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. Expertise in Clinical Trials Monitoring (0 a 3.5 points)
- 2. Previous experience in Clinical Trials Units within Public Health System (0 a 3.5 points)
- 3. High level of Office and Good communication skill in English (0 a 2 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: **7th July 2019**

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- To prepare, present and follow up the documentation directed to the mRECs and Regulatory Authorities, from project start-up to completion.
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- To make the initial visit and train the research team in the project activities.
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Date: **2nd July 2019**

Instituto de Investigación Sanitaria San Carlos (IdISSC)
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