Position: **Clinical Project Manager**

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Private Foundation Món Clínic Barcelona

We are a private, newly created, and non-profit Foundation, linked to the Hospital Clinic de Barcelona, whose mission is to strengthen people's health and improve the quality of life of citizens. To respond to our founding goals, we have a CRO for conducting clinical studies, initiated by the pharmaceutical industry or by researchers, both in the field of medicine and medical devices, offering a comprehensive portfolio of services to meet the needs of our customers.

Definition:

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.

Areas of Responsibilities/Roles:

- To act as the main contact of the sponsor throughout the project, if so designated.
- To contribute to the process of drafting the protocol in those aspects that influence its practical execution, and in other aspects in which he/she is experienced.
- 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 and deadlines.
- 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 Trial Master File.
- To coordinate all the regulatory documents of the research project.
- To supervise and assist the internal or external monitoring team.
- To supervise the monitoring activities carried out by the monitors and CRA manager.
- 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.
- 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.

Requirements:

- University education, preferentially in science, and preferably in life sciences, or with complementary studies related to project management.
- Master's or postgraduate training in Clinical Trials is a plus.

Valuable:

- Specific training in monitoring Clinical Trials or evidence of experience. Training in Good Clinical Practices or evidence of experience.
- Training in project management is a plus.

Experience needed:

- Minimum of 3 years' experience in the clinical research in the hospital, pharmaceutical or biotechnology environment, developing monitoring, research, or related management activities, or fewer years' experience if the activity will be supervised by a senior manager.

Skills:

- High level of English.

Working conditions:

- Full time position
- Offices located in the center of Barcelona
- Home office possibility
- Salary range – to determinate
- Starting date of the contract: April 2024.

If you are interested in this offer, please send your CV to the following email: **amiralles@fundaciomonclinicbarcelona.cat**