JOB OFFER

MIMARK

Clinical Manager

MiMARK is an IVD/startup company focused on improving Women's Health. We are specialized in the development and validation of clinically impactful biomarkers in gynecological fluids to provide with innovative diagnostics across gynecology indications. In MiMARK we envision these fluids as the next step liquid biopsy in the gynecological arena to provide easy to access and reliable diagnostics

Our first product, WomEC, is an IVD for a high-efficiency diagnosis of endometrial cancer. Our product is currently in the last steps of prototype development (immunoassay-based technology), and we aim entering clinical validation phases by 2023.

We are seeking for you!

We are seeking an individual with a high level of expertise in Clinical Trials, with a specific focus in the clinical validation of IVD products.

As a clinical manager, you will be Responsible for planning and executing clinical trials in Europe and USA. Including the preparation, review and approval of all associated documentation (regulatory, protocol, report, timelines, study plans, communication, vendors, monitoring, safety, statistical, data management, technical specifications, IMP related documents, and any other study-related documentation).

Those are critical steps in the development and marketing of new IVDs for MIMARK.

You will be an integral part of the MiMARK team and will contribute to the company efforts to move from R&D to clinical validation of our assets and their regulatory approval.

Responsibilities

- Participate to strategic planning of clinical studies.
- Establish the trial plan (organization, structure, timelines, budget) and management of project budgets, including approval of invoices payment and forecast planning.

- Implement the trial plan either in-house or through selection and supervision of a CRO, in compliance with the quality, regulatory and ethical requirements.
- Responsible for clinical trial objectives achievement (feasibility, recruitment, budget, timelines, quality).
- Participate in the preparation of any documentation related to competent national and local authorities, and the relevant ethics committees, coordinate and boost regulatory submissions and answer their questions.
- Organize and leading vendor selection.
- Contribute to the development of a network of international experts and KOL in the field of women's health for clinical or research collaborations.
- Collaborate with the other MiMARK departments to foster a patient-centric culture.
- Supervise and boost sites activation and recruitment progress, database cleaning, and timely SAE reporting. Review of the Trial Master File key documents related to activities under ICTM direct responsibility.
- Collaboration in the planning and conduction of audits and CAPA implementation, and in the inspections to the participating sites or sponsor.
- Ongoing review of clinical blinded data (e.g. for identification of protocol deviations, ensuring accuracy of data cleaning, early detection of unexpected trends on patients baseline characteristics).
- Contribute to the identification of potential candidate biomarkers in the field of women's health.
- Publication planning and preparation.
- Reporting to the CEO

Requirements

- Pharmacy or Science Degree (PhD is desirable but not mandatory)
- Clinical Trial experience, both operationally and for management (required)
- Experience in IVD clinical validation studies
- Track record in managing clinical studies, CRO, Academic Research Organization, relationships with clinical stakeholders, both nationally and Internationally
- Fluency In English (as we aim to recruit in EU and US countries)

- Experience in oncology and/or women's health (desirable, but not mandatory)
- Budget management experience
- Knowledge of GCPs and legislation on clinical trials in EU and US
- Proficient in project management and entrepreneurial spirit
- Passionate, well-organized, decisive, and committed
- Flexibility to travel.

Benefits

We would like you to profit from joining a team of talented people that share the passion to develop minimally invasive diagnostics based on gynecological fluids to improve women health. We would like to offer you a competitive compensation package:

- Full time job (preferred)
- Compelling salary and incentive package
- Great location in Barcelona (hybrid or remote work will be considered)
- Flexible working hours, since we aim to balance reconciliation of work and personal life with work responsibilities
- Entrepreneurial environment and great team!
- The person who joins the company will be able to develop his or her professional career within an expanding StartUp.

Selection process

The selection process will consist of a merit-based procedure. In brief, we will first check the eligibility criteria based on the candidate's CV and by considering the requirements described in this job offer. Those passing this check will be interviewed. The selected candidate will be officially invited to join MiMARK's team.

How to apply

If you are passionate in joining us,

contact us by sending your CV and motivation letter including 2 referees' contact details to hello@mimark.es

Please indicate the following reference in the subject email: "MIMARK Clinical Manager job application"

We look forward to receiving your application before May 19th

17th April 2023