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Clinical Operations Coordinator

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Company: Nacre Capital

Location: Argentina

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Clinical Operations Coordinator

Fairtility

Fairtility, as one of Nacre capital portfolio companies, combines clinical excellence, with cutting edge AI technology and strong business leadership to revolutionize reproductive care, supporting fertility clinics, health care professionals and their patients with AI and data-driven insights to augment decision-making and enhance outcomes.

Our offering includes an AI-powered support software platform that provides clinicians and lab personnel with automated and comprehensive assessments of embryo viability and egg-quality together with various clinical and operational insights that streamline data utilization and communication within and outside of the fertility clinic.

We are seeking an experienced Clinical Operations Specialist to play a pivotal role in leading and coordinating various aspects of clinical trials. The role involves responsibilities ranging from communication with clinical sites, execution of contracts, study administration, regulatory considerations, data collection and study closure, ensuring adherence to clinical study regulations, including Good Clinical Practice (GCP) guidelines and Institutional Review Board (IRB) requirements throughout the entire clinical trial lifecycle.

Key Responsibilities:

1. Study Administration

• Oversee and manage study administration in accordance with Good Clinical Practice (GCP) guidelines.

• coordinate and oversee all study-related tasks to ensure efficient execution and adherence

to timelines.

• Interface with Institutional Review Boards (IRBs) to draft submissions, obtain approvals and ensure ongoing compliance.

• Create and maintain Trial Master File (TMF) and related recodes.

2. Communicate with sites

• Establish and maintain effective communication channels with study sites.

• Facilitate contract negotiations with study sites, ensuring compliance with regulatory and organizational standards.

• Provide training to site personnel.

3. Ongoing data collection

• Develop and implement data collection strategies and processes in collaboration with study teams.

• Monitor and ensure the quality and completeness of collected data.

4. Protocol design and development

• Support study protocol creation while representing GCP and regulatory considerations and procedural aspects.

• Collaborate cross-functionally with Clinical Affairs, Medical Affairs and Regulatory Affairs teams throughout the planning and execution phases.

5. Study closure:

• Coordinate the closure activities of clinical trials in compliance with regulatory requirements.

• Compile study documentation for archiving and regulatory submissions.

Requirements

Qualifications and Skills:

• Bachelor's degree in a relevant field (e.g., life sciences, nursing, pharmacy, medical sciences).

• Proven experience in clinical affairs within the medical device, preferable software experience.

• In-depth knowledge of Good Clinical Practice (GCP) guidelines and regulatory requirements related to clinical trials.

• Strong organizational, operational and communication skills.

• Ability to manage multiple tasks and prioritize effectively.

• Familiarity with data collection systems and electronic data capture tools – advantage.

• Excellent verbal and written English.

• CRA certificate – advantage

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