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CRA - all levels

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Company: Fortrea

Location: Buenos Aires

Category: computer-and-mathematical

As a leading global contract research organization (CRO) with a passion for scientific rigor and decades of clinical development experience, Fortrea provides pharmaceutical, biotechnology, and medical device customers a wide range of clinical development, patient access and technology solutions across more than 20 therapeutic areas. With over 19,000 staff conducting operations in more than 90 countries, Fortrea is transforming drug and device development for partners and patients across the globe.

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Essencial job duties

·Responsible for all aspects of study site monitoring including routine monitoring and close-out of clinical sites, maintenance of study files, conduct of pre-study and initiation visits; liaise with vendors; and other duties, as assigned

·Responsible for all aspects of site management as prescribed in the project plans

·General On-Site Monitoring Responsibilities

·Ensure the study staff who will conduct the protocol have received the proper materials and instructions to safely enter patients into the study

·Ensure the protection of study patients by verifying that informed consent procedures

and protocol requirements are adhered to according to the applicable regulatory requirements

·Ensure the integrity of the data submitted on Case Report Forms (CRFs) or other data collection tools by careful source document review

·Monitor data for missing or implausible data

·Ensure the resources of the Sponsor and Labcorp are spent wisely by performing the required monitoring tasks in an efficient manner, according to SOPs and established guidelines, including managing travel expenses in an economical fashion according to Labcorp travel policy

·Ensure audit readiness at the site level

·Travel, including air travel, may be required and is an essential function of the job.

·Prepare accurate and timely trip reports Responsible for all aspects of registry management as prescribed in the project plans

·Undertake feasibility work when requested

·Participate in and follow up on Quality Control Visits (QC) when requested

·Recruitment of potential investigators, preparation of EC submissions, notifications to regulatory authorities, translation of study-related documentation, organization of meetings and other tasks as instructed by supervisor

·Might be requested to work in a client facing environment

·Track and follow up on Serious Adverse Event (SAE) reporting, process production of reports, narratives and follow up of SAE

·Independently perform CRF review; query generation and resolution against established data review guidelines on Labcorp or client data management systems as assigned by management

·Assist with training, of new employees, e.g. co-monitoring

·Coordinate designated clinical projects as a Local Project Coordinator

Main requirements

·University or college degree, or certification in a related allied health profession from an appropriately accredited institution (e.g., nursing licensure).

·Thorough knowledge of ICH Guidelines and understanding of local regulatory requirements

·Strong experience with Clinical Monitoring experience

·Ability to monitor study sites independently according to protocol monitoring

guidelines, SOP, and local regulatory Guidelines

·Have a full understanding of the Serious Adverse Event (SAE) reporting, process production of reports, narratives and follow up of SAEs

·Good planning, organization, and problem- solving abilities

·Ability to work with minimal supervision

·Good communication and interpersonal skills

·Good analytical and negotiation skills

·Computer competency

·Fluent in local office language and in English, both written and verbal

·Works efficiently and effectively in a matrix environment

Ps: all positions are eligible for people with disabilities.

Fortrea is actively seeking motivated problem-solvers and creative thinkers who share our passion for overcoming barriers in clinical trials. Our unwavering commitment is to revolutionize the development process, ensuring the swift delivery of life-changing ideas and therapies to patients in need. Join our exceptional team and embrace a collaborative workspace where personal growth is nurtured, enabling you to make a meaningful global impact.

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