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FSP CRA I (Taipei)

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Company: Fortrea

Location: Taipei

Category: other-general

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.

Site monitoring and site management responsibility for clinical studies according to Company, and/or Sponsor, Standard Operating Procedures, and Regulatory Guidelines. Assures the implementation of project plans, as assigned.

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

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

3) General On-Site Monitoring Responsibilities:

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

5) Ensure the protection of study patients by verifying that informed consent procedures and protocol requirements are adhered to according to the applicable regulatory requirements

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

7) Monitor data for missing or implausible data

8) Ensure the resources of the Sponsor and Fortrea 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 Fortrea travel policy

9) Ensure audit readiness at the site level

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

11) Prepare accurate and timely trip reports

12) Interact with internal work groups to evaluate needs, resources and timelines

13) Act as contact for clinical trial supplies and other suppliers (vendors) as assigned

14) Responsible for all aspects of registry management as prescribed in the project plans

15) Undertake feasibility work when requested

16) participate in and follow-up on Quality Control Visits (QC) when requested

17) 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 as assigned 18) Assist Senior CRA with managing investigator site budgets

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

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

21) Assist with training, mentoring and development of new employees, e.g. co-monitoring

22) Coordinate designated clinical projects as a Local Project Coordinator (with supervision, if applicable), and may act as a local client contact as assigned

23) Perform other duties as assigned by management

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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