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CRA (Level II)

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Company: Thermo Fisher Scientific

Location: Ghana

Category: other-general

Performs and coordinates different aspects of the clinical monitoring and site management process. Conducts remote or on-site visits to assess protocol and regulatory compliance and manages required documentation. Manages procedures and guidelines from different sponsors and/or supervising environments (;FSO, FSP, Government, etc.). Acts as a site processes specialist, ensuring that the trial is conducted in accordance with the approved protocol, ICH-GCP guidelines, applicable regulations and SOPs to guarantee subjects rights, well-being and data reliability. Ensures audit readiness. Develops collaborative relationships with investigational sites. Detailed tasks and responsibilities assigned to role are outlined in the task matrix.

Key responsibilities:

Monitors investigator sites with a risk-based monitoring approach,applies root cause analysis (RCA), critical thinking and problem-solving skills to identify site processes failure and corrective/preventive actions to bring the site into compliance and decrease risks.

Ensures data accuracy through SDR, SDV and CRF review as applicable through on-site and remote monitoring activities.

Assess investigational product through physical inventory and records review. Documents observations in reports and letters in a timely manner using approved business writing standards.

Escalates observed deficiencies and issues to clinical management expeditiously and follow all issues through to resolution.

May need to maintain regular contact between monitoring visits with investigative sites to confirm that the protocol is being followed, that previously identified issues are being resolved and that the data is being recorded in a timely manner.

Conducts supervising tasks in accordance with the approved monitoring plan.

Participates in the investigator payment process. Ensures a shared responsibility with other project team members on issues/findings resolution.

Investigates and follows-up on findings as applicable.

Participates in investigator meetings as vital. Identifies potential investigators in collaboration with the client company to ensure the acceptability of qualified investigative sites.

Initiates clinical trial sites according to the relevant procedures to ensure compliance with the protocol and regulatory and ICH GCP obligations, making recommendations where warranted. Performs trial close out and retrieval of trial materials.

Ensures that required crucial documents are complete and in place, according to ICH-GCP and applicable regulations. Conducts on-site file reviews as per project specifications.

Provides trial status tracking and progress update reports to the Clinical Team Manager (CTM) as required.

Ensures study systems are updated per agreed study conventions (;Clinical Trial Management System).

Facilitates effective communication between investigative sites, the client company and the PPD project team through written, oral and/or electronic contacts.

Responds to company, client and applicable regulatory requirements/audits/inspections.

Maintains & completes administrative tasks such as expense reports and timesheets in a timely manner.

Contributes to the project team by assisting in preparation of project publications/tools, and sharing ideas/suggestions with team members.

Contributes to other project work and initiatives for process improvement, as required.

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