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Clinical Trial Coordinator

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Company: Thermo Fisher Scientific

Location: Ghana

Category: other-general

Provides administrative and technical support to the Project Team. Supports audit readiness by ensuring files are reviewed on schedule detailed in the organization's SOPs and department guidance documents.

Performs department, Internal, Country and Investigator file reviews as assigned and documents findings in appropriate system

Ensures allocated tasks are performed on time, within budget and to a high-quality standard

Proactively communicates any risks to project leads

Supports the maintenance of study specific documentation and systems including but not limited to: study team lists, tracking of project specific training requirements, system access management, and tracking of project level activity plans in appropriate system

Provides system support to study teams.

Supports Risk Based Monitoring activities

Performs administrative tasks on assigned trials including but not limited to: timely processing of documents sent to Client (electronic) Trial Master File (eTMF) as assigned, performing (e)TMF reviews, performing mass mailings and communications as needed, providing documents and reports to internal team members.

Supports scheduling of client and/or internal meetings

Reviews and tracks local regulatory documents.

Transmits documents to client and centralized IRB/IEC

Analyses and reconciles study metrics and findings reports.

Assists with clarification and resolution of findings related to site documentation.

Maintains vendor trackers.

Assists with coordination, compilation and distribution of Investigator Site File (ISF) and Pharmacy binder materials and non-clinical study supplies to site.

Assists with study-specific translation materials and translation Quality Control (QC) upon request.

Other responsibilities may include, but are not limited to:

Providing administrative support for site-initiated amendments and site supply shipments

Manage couriers.

Supporting CRAs in visit preparation

Supporting Clinical Manager/Project Managers in country project related expenditures

Assist in translation and translation QC.

Distribute country and site level communications.

Create and maintain investigator list.

QC of country and site-level documents

Submission of complete country and site-level documents to eTMF and related tracking in Clinical Trial Management System (CTMS)

Performs document tracking in CTMS, verifies appropriate country or site level activity plans are applied, updates country level activities/documents for amendments.

Print, compile and distribute ISF and Pharmacy binder to site prior to Site Initiation Visit (SIV)

Review eTMF reports and dashboards to identify country and site level essential documents statuses.

Follow up on outstanding/missing study documents to be sent to site.

Forward wet ink documents retrieved from sites.

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