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We are hiring!

Sr Central Monitor/Central Monitor

#1716835

PURPOSE

To ensure the work is conducted as per SOPs, Policies and Good clinical practice's and applicable regulatory requirements. Adherence to protocol, overall completeness, and readiness of the supplied patient information to the next level of patient review and follow the metrics and timelines.

RESPONSIBILITIES

- Perform centralized monitoring activities on assigned projects and evaluate the quality and integrity of the study as per the protocol, SOPs respective regulation and guidelines.
- Ensure accurate completion and maintenance of internal systems, databases, tracking tools for the project specific information.
- May perform Management of triggers and preparation of i-site pack for respective sites and countries for assigned study(ies).
- May assist in Developing required basic data analytics scope and performing the trend analytics for their respective studiy(ies).
- May participate in (study) team meetings and interaction with cross functional staff to verify information and/or triage new data issues or prior identified action items
- Escalate quality issues pertaining to site to respective Centralized monitoring lead/ Sr. Central Monitor.
- May perform Subject Level Data Review that require further investigation with the clinical site to determine overall accuracy (inclusion & exclusion criteria/ IP/AE/ Labs/EOT/EOS/ End points/SAEs etc.) Review any other information as necessary to determine overall readiness of the patient information for next level review
- May Act as back up for Sr. Central Monitor.

REQUIRED KNOWLEDGE, SKILLS AND ABILITIES

- Advanced knowledge of clinical trial conduct, and skill in applying applicable clinical research regulatory requirements; i.e., ICH GCP and relevant local laws, regulations and guidelines, towards clinical trial conduct. Familiarity with related systems and software utilized in clinical operations.
- Strong written and verbal communication skills including good command of English language
- Results and detail-oriented approach to work delivery and output
- Ability to work on multiple projects and manage competing priorities
- Ability to establish and maintain effective working relationships with coworkers, managers and clients
- Good planning, time management and prioritization skills
- Good software and computer skills, including MS Office applications including but not limited to Microsoft Word, Excel and PowerPoint
- Ability to work across cultures and geographies with a high awareness and understanding of cultural differences

MINIMUM REQUIRED EDUCATION AND EXPERIENCE

Bachelor's degree in clinical, life sciences, mathematical sciences, or related field, or nursing qualification, with 1 years of relevant work experience or equivalent combination of education, training and experience.