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**Executive / Assistant Manager - Clinical Operations (Clinical Research Associate)**

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Company: Viatris

Location: bangalore

Category: other-general

Position Title : Executive / Assistant Manager - Clinical Operations (Clinical Research Associate)

Location : Bangalore

At VIATRIS™, we see healthcare not as it is but as it should be. We act courageously and are uniquely positioned to be a source of stability in a world of evolving healthcare needs.

Viatris empowers people worldwide to live healthier at every stage of life.

We do so via :

Access – Providing high quality trusted medicines regardless of geography or circumstance.

Leadership – Advancing sustainable operations and innovative solutions to improve patient health; and

Partnership – Leveraging our collective expertise to connect people to products and services.

Every day, we rise to the challenge to make a difference and here's how this role will make an impact.

Role Purpose

The incumbent will work with Global Clinical Operations and Data Management teams to execute clinical research studies and provide data management deliverables at established and

new Contract Research Organizations (CROs). This individual will ensure the proper monitoring, completeness, timeliness and quality of complex research studies and meet internal data reporting needs according to Good Clinical Practice (GCP), departmental Standard Operating Procedures (SOPs) and applicable regulations.

Perform job functions in accordance with all applicable Standard Operating Procedures (SOP), federal and state laws, health authority regulations/policies, and departmental processes.

Key Responsibilities
Function as monitoring lead for assigned clinical Phase I-IV studies. Serve as liaison between the Mylan project team (Global Clinical Operations, Data Management, Clinical Science, Quality Assurance, etc.), Clinical Research Organizations (CROs), and clinical investigators regarding study activities to include the scope of the clinical study; data review, project time lines, and requests for documentation.
Perform comprehensive data management tasks and monitoring functions. Assist in the preparation of project plans and provide project reports to management as needed. Conducts data review, writing reports and resolving data clarifications.
Function as clinical data reviewer for multiple Phase I-IV focused CROs with responsibility to oversee assigned projects assigned to that CRO. Ensure the CRO is compliant with assigned study protocols, overall clinical objectives, GCP, SOPs and applicable federal, state and local requirements. Maintain all required regulatory study documents, monitoring records and correspondence confidentially and in accordance with Mylan document control procedures for assigned studies.
Review clinical and drug product documents for accuracy, completeness and timeliness internally and at the research sites. This includes review of completed source documents (including eDiary, DCFs, NTFs, etc.), Regulatory Documents, Drug Release/Accountability paperwork, Source Document templates, Case Report Form (CRF) templates, Informed Consent Forms, Adverse Events, Dosing Logs, Protocol Deviations, completed CRFs and Clinical Reports.
Conduct clinical monitoring of studies remotely and on-site as required according to Mylan SOPs and Clinical Monitoring Plan (CMP). This includes visit preparation, monitoring process, completion of the monitoring report, visit follow-up activities and travel to and from

the clinical locations.
Interview clinical site research personnel in follow-up of monitoring visits and data issues. Communicate any substantial findings to his/her supervisor and clinical investigator during or immediately following a monitoring visit. Monitor and/or follow-up on the implementation of corrective action plans following clinical site inspections or audits, as required.
Develop and review SOPs where required. Responsible for identifying improved operational methods for functional area.
Oversee and assist in training of new Clinical Data Reviewer where required.
Perform other duties as assigned.

Qualifications & Experience
KNOWLEDGE
Must possessknowledge of project management and data management skills and monitoring of clinical studies. Knowledge of and understanding of Good Clinical Practice and other associated regulations, guidelines and industry standards for clinical trials is required. Knowledge of medical terminology is desired.

SKILLS AND ABILITIES
Must possess excellent oral and written communication skills. Good organizational skills, attention to detail, ability to work as part of a team and the ability to manage multiple tasks is required. Must possess planning skills for a range of 6 months to 2 years in advance of study deadlines. Should be proficient in PC applications (Excel, Microsoft Word, etc.). Should have the ability to read and interpret documents. Ability to write routine reports and correspondence. The successful candidate must maintain a high level of professionalism and personal integrity

SUPERVISION
Position functions primarily autonomouslyand acts as a mentor to other Clinical Data Reviewers.

EDUCATION/EXPERIENCE
Minimum of a Bachelor's degree (or equivalent) and 2-4 years of experience in the field as monitor. Prefer 4-6 years of experience in the field. However, a combination of experience and/or education will be taken into consideration.

LICENSES/CERTIFICATIONS

Certification (i.e., ACRP) as Clinical Research Associate preferred, but not required.

LANGUAGE SKILLS

Ability to read and interpret complex business and/or technical documents. Ability to write comprehensive reports and detailed business correspondence. Ability to work with groups of people such as other departments and communicate known concepts. Ability to present to a group or department.

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