

Central Monitoring Associate Manager

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Company: Fortrea

Location: Mexico City

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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.

Job Summary

The Central Monitoring Associate Manager is responsible for the execution of key Central monitoring (site, subject & study level review as applicable) activities. The Central Monitoring Associate Manager collaborates within a matrix environment, communicates proactively internally and externally and across functions with key stakeholders to ensure Central Monitoring is proactively and effectively executed to meet client expectations. Central Monitoring Associate Manager may be responsible for the preparation and conduct of Central Monitoring tasks across a series of sponsor projects commencing with Informatics platform launch up to study reporting. Central Monitoring Associate Manager conducts review of the applicable Informatics platform and communicates findings at the country, study, site, subject level. The Central Monitoring Associate Manager provides Central monitoring support to the study team and to the client. The Central Monitoring Associate Manager requires working knowledge of broader drug development and clinical trials. He/she is responsible for the conduct of central monitoring activities in a timely manner. Oversee the trial progress as per the defined plan and notify any changes/risk and

escalate as appropriate.

Essencial Job Duties

Performs the Central monitoring activities for multiple studies for customers and ensure accurate tracking and status reporting of studies in his/her remit.

Act as the Lead for the Central Monitoring team for more than one studies for multiple customers

Support Manager and leadership in preparation of detailed study risk assessment and in Sponsor presentations / bid defenses.

Ensures that tracking and status reporting are performed in a timely and accurate manner.

Contributes to the Risk Assessment and Categorization Tool(RACT) for topics related to central Monitoring and/or medical reviews and considers risks when planning tools configuration

Supports the Data Expert with Critical Data and Process Definition and EDC design implementation

Supports the development of informatics Platform requirements, including design of the visualizations, taking into consideration the data feeds for the study (EDC, laboratory, etc.)

Collates requirements including prescriptive risk factor mitigation strategies, SDV strategy, study-specific risk factor definition, variable risk factor trigger levels.

Draft the Configuration Plan and all other applicable Plans in collaboration with the study team and update these on an ongoing basis including the refinement of visualizations and any edits in line with emerging risk profile and study changes.

Edits the Central Monitoring and other applicable plans in line with emerging risk profile and study changes.

Populates the tools, tests variable risk factors, adjusts trigger levels, study specific risk factors and central monitoring parameters.

Performs ongoing reviews, prepares and recommends mitigation actions and reviews recommended monitoring levels with project team and ensures that identified issues are followed to resolution

Proposes potential changes to monitoring intervention level on behalf of the project team in line with overall strategies

Prepares and distributes the Project/Study Reports at intervals during study conduct and at study close out.

Main requirements

University / college degree or post-graduation (life science preferred) from an appropriately accredited institution.

Minimum of 6-8 years of relevant clinical research experience in a pharmaceutical company/CRO or other equivalent experience with increasing levels of responsibility in clinical trial related roles e.g. project management, clinical monitoring, data management and informatics.

Fluent English

End to End RBQM experience is preferred

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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