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Senior Central Monitoring Analyst - Remote

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Company: Thermo Fisher Scientific

Location: Argentina

Category: production

PPD, part of Thermo Fisher Scientific centralized monitoring group delivers a new approach to risk surveillance and centralized statistical monitoring, combining the power of statistical and analytical tools with expertise from operationally experienced staff to monitor and manage clinical study data. Centralized monitoring staff explores study data holistically to pinpoint meaningful signals, resulting in more efficient and effective issue resolution and a proactive approach to risk detection. Using this data-driven approach, PPD can address study problems or site performance quickly, directing remediation activities where needed and positioning on-site monitoring activity in a targeted approach.
Centralized monitoring is an integral part of PPD’s risk-based monitoring (RBM) strategy and supports centralized monitoring efforts. Ongoing data assessments from our centralized monitoring group allows to adapt monitoring plans dynamically so that CRAs can focus on the factors that have the greatest impact on data integrity and subject safety. Regardless of the percentage of source data verification (SDV), the centralized monitoring group's centralized statistical monitoring approach identifies risk signals that may be difficult to detect through traditional review methods, such as on-site monitoring.
Centralized monitoring evaluates data within and across studies, sites, countries and regions. Our analytic approach provides insight into:
Data errors, deviations

Trends, outliers

Unusual variation (or lack of variation)

Potential data manipulation, fraud

Other systematic errors or data integrity issues.

As a Senior Centralized Monitoring Analyst, you'll be supporting centralized statistical and risk surveillance activities on assigned trials.
At PPD we hire the best, develop ourselves and each other, and recognize the power of being one team. We offer continued career advancement opportunities, award winning training and benefits focused on the health and wellbeing of our employees.
Summarized Purpose:
Acts as a subject matter expert and interdepartmental and client liaison for centralized monitoring activities. Area of focus may be a centralized monitoring specialty, focusing on the development of tools and processes to detect, investigate, diagnose and mitigate issues and risks, or a project lead for one or more projects, including set-up of functional plans, tools and delivery of review cycles.
Essential Functions:
Ensures performance of assigned reviews with high quality, on-time results with more complex analyses or deeper root cause analyses to connect related signal to risks.

Provides training and guidance to junior team members.

May participate in a project lead or development specialist role, or a combination of both.

Project leadership activities include: Leads the design and setup of study specific tools and centralized monitoring plan for data review; manages review timelines, develops analysis assignments for team, and supports budget management; organizes, communicates with internal team, and delegates as appropriate to ensure reviews are completed on-time, on budget, with high quality; assists with report development, delivers reports, and leads centralized monitoring meetings; contributes to risk assessment through the completion of the department risk assessment tools. Participates in the cross-functional risk assessment review meetings and contributes to overall risk planning.

Specialist activities included focused efforts on the development of new tools and analyses within area of specialty.

Education and Experience:

Bachelor's degree or equivalent and relevant formal academic / vocational qualification

Previous experience that provides the knowledge, skills, and abilities to perform the job (comparable to 5+ years'). Prior experience in clinical monitoring, data management, biostatistics or related field in support of clinical trials is preferred.

In some cases, an equivalency, consisting of a combination of appropriate education, training and/or directly related experience, will be considered enough for an individual to meet the requirements of the role.

Knowledge, Skills and Abilities:

Capable of applying in-depth knowledge and skills in a highly organized fashion while adhering to regulatory guidelines, global SOPs and client expectations

Strong attention to detail and skill with numbers

Substantial analytical /problem-solving skills /judgment in decision making

Ability to work independently and organize and coordinate activities across the team

Demonstrated ability to maintain a high degree of confidentiality with clinical data and client's proprietary data

Proven flexibility and adaptability

Ability to work and lead in a team environment and independently

Strong oral and written communication skills (English) with the ability to communicate effectively with a variety of internal and external customers, including project team, functional management and client contacts

Strong computer skills, with solid knowledge of MS Office (Word, Excel, PowerPoint) and the ability to learn and use interactive computer systems

Complete ability to extract pertinent information from standard study documentation, such as protocols, electronic study data systems and to identify trending of site/study data

Solid prioritization skills with ability to plan, monitor and manage workload fluidly in response to changing project demands

Comprehensive understanding of project protocol, project documentation including Centralized Monitoring Plan and other functional plans

Ability to serve as a subject matter expert and lead on projects cross-functionally

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