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PAREXEL launches clinical trial data monitor solution

May 21, 2014 | News | By BioSpectrum Bureau



Singapore: PAREXEL International has launched an integrated suite of applications for managing clinical trials called Perceptive MyTrials Data-Driven Monitoring solution.

On-site monitoring is a critical aspect of trial management, with the primary function of identifying and mitigating patient safety or data quality risks at investigative sites. The U.S. Food and Drug Administration (FDA) and other regulatory bodies have issued guidance to assist sponsors in developing risk-based monitoring strategies that enhance patient protection and improve trial data quality through more effective study oversight. They have encouraged greater use of centralized monitoring methods to evaluate clinical trial conduct and progress.

PAREXEL's new data-driven monitoring solution provides approach to centralized risk-based monitoring. The technology captures, consolidates and organizes clinical information in real-time from disparate sources. As a result, drug developers can accurately identify study risks and rapidly determine what type of intervention may be required. Monitoring focused on specific risk offers the potential to enhance patient safety, reduce costs and promote regulatory compliance.

"Perceptive MyTrials Data-Driven Monitoring uses clinical data to guide monitoring activities as an alternative to periodically scheduled monitoring visits, which can be time-consuming, costly and inefficient," said Mr. Xavier Flinois, President of PAREXEL Informatics. "Greater insight into study data allows for a more precise determination of when on-site monitoring visits need to occur and what activities should be undertaken during those visits. This can make clinical trial participation safer for patients while offering cost efficiencies for sponsors."

"Our data-driven monitoring solution builds on PAREXEL's long-standing track record of developing innovative technologies to continuously improve clinical processes," said Mr. Mark A. Goldberg, President and Chief Operating Officer, PAREXEL. "Perceptive MyTrials Data-Driven Monitoring represents the latest example of our leadership in bringing efficiencies to the drug development process."