MEDIDATA | WHITE PAPER

360° Monitoring: A New Approach to Dynamic Clinical Oversight Using Centralized Insights

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Medidata has long been recognized as the industry leader and innovator in clinical trials solutions. Over the decades, it has achieved many industry firsts, including forming industry and patient feedback boards and developing new concepts, technologies, and services.

In a landmark presentation, Olgica Klindworth, VP, Data Quality and Risk Management Solutions, and Lauren Price, Director, CTMS Product Management, unveiled a new Risk-Based Quality Monitoring (RBQM) concept called 360° Monitoring at the annual Summit for Clinical Ops Executives (SCOPE) in Orlando, Florida, in February 2025.

The concept takes a new approach to RBQM methodologies and strategies, combining Medidata's existing integrated platform of technologies, its clinical trial database, which is the largest in the industry, automation including AI and GenAI approaches, leveraging global advancements in healthcare data interoperability and adding further innovative ideas and processes to operationalize a new quality management framework for monitoring.

A background in existing monitoring practices will provide (perhaps shocking) context for understanding the true impact of this revolutionary concept.

The *Journal of Clinical and Translational Science* (2024) estimated that 46% to 50% of time in a clinical trial is attributed to Source Data Verification (SDV) and an average of 25-40% of clinical trial costs.[1]