

research allows researchers to capture accurate and on-time quality issues and generate transparent quality metrics. The indicators arising from quality metrics will help to improve quality of the research across SingHealth Institutions. METHODOLOGY

The information generated from Risk-Based Monitoring (RBM) in clinical

From Risk-Based Monitoring to

Metric Reporting in Clinical Research

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Protocol review and study risks assessment are performed. Monitoring strategies based on risk profile of the research is defined.

Critical items and processes are reviewed at site.

Protocol Deviation/Non-Compliance (PD/NC), unreported Serious Adverse Event (SAE), actions and recommendations are captured and followed up.

Monitoring Report & QI Plan

Monitoring plan

On-site visit



Quality metrics will be generated from data extracted from QI plan for further analysis. Trend analysis will be performed regularly to identify and mitigate risk/gaps and establish relevant trainings for researchers

Metrics & Trend analysis

The risk-based approach to monitoring allows identification of systemic quality issues and timely implementation of corrective and preventive actions.

Risk indicator data review, risk and issue tracking, management, and analysis allow identification of the deficiencies in research compliance and establishes training needs to raise awareness.

Overall risks in clinical research at study and site level will be



mitigated via establishment of operational workflows and risk controls.

Conclusion



A comprehensive solution that combines access to data, basic analytics and seamless integration with other available research information will be presented. The results provide strong evidence that our RBM methodology can improve the clinical oversight process across SingHealth clinical research in an efficient manner.