Innovative Approaches to Clinical Research Monitoring: The Power of Ingenuity at Memorial Sloan Kettering Cancer Center

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BACKGROUND

The Risk-Based Monitoring (RBM) approach prioritizes oversight of clinical trials based on potential risk to study data quality and patient safety. At Memorial Sloan Kettering Cancer Center (MSK), the number of active institutional therapeutic and diagnostic studies has increased one hundred and seventy-nine percent (179%) in the last three (3) years, accruing over four thousand-seven hundred (4,700) participants in 2022.

It is crucial to design strategies that maximize the power of monitoring to increase the reach of monitors to identify and mitigate risks to data quality and patient safety, while improving the efficiency of monitoring.

GOALS

1. Maximize the efficiency of an RBM strategy to ensure proper oversight of Investigator Initiated Trials (IITs).
2. Streamline the review of critical study areas such as eligibility and informed consent procedures by optimizing the process to reach as many participants as possible.

METHODS

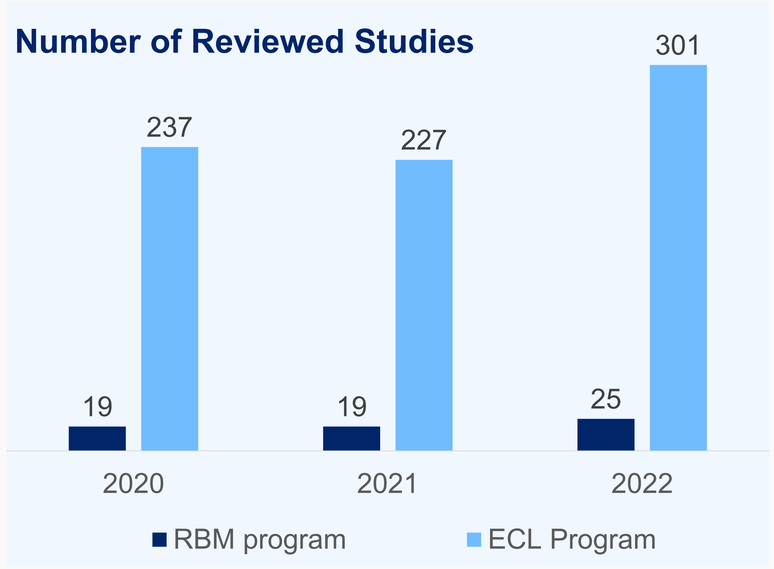
The Clinical Research Quality Assurance (CRQA) Monitoring team developed and implemented a multidisciplinary RBM strategy aimed to identify areas that pose the highest risk to participant safety and data quality while minimizing low yield monitoring activities through process automation. The following priorities have been established.

1. High-risk studies – RBM of IIT portfolio: A risk assessment tool selects single-center IITs for which a customized RBM plan is developed. Study participants are reviewed based on a targeted source data verification (TSDV) calendar focused on primary and secondary study endpoints.
2. High-risk processes – Eligibility Checklist (ECL) Verification Review: A randomized sample of research participants undergo an independent review to ensure that registration and eligibility procedures are followed and are compliant with internal and federal regulations.
3. Low-yield monitoring activities: Process automation minimizes the possibility of deficiencies and the need for broad monitoring, focusing on compliance areas instead of transcription errors.

Method #1: RBM Program

Method #2: ECL Program

Method #3: Process Automation



RESULTS

Our strategy has allowed prioritization of monitoring activities, selecting high risk studies for customized RBM monitoring, and broad oversight of high-risk processes shared by clinical trials, such as eligibility and informed consent. Additionally, process automation has helped identify areas where monitoring can be reasonably waived without impacting safety.

This innovative approach to RBM has allowed the seven (7) members of the CRQA Monitoring team to oversee more than three hundred (300) different studies and more than one thousand (1,000) study participants in one year, providing an additional layer of oversight of participant safety and data quality.

Additionally, the findings identified during these reviews have helped direct education efforts across MSK, further increasing the reach of quality assurance compliance.

CONCLUSION

A multidisciplinary approach to monitoring can reduce the need for extensive visits and increase efficiency tailoring monitoring activities to the areas of highest risk. While some automation of processes has already been achieved, a true integration between the Electronic Medical Record (EMR) and Case Report Forms (CRFs) will furthermore streamline monitoring activities.

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