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.

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.

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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