

Too Many Studies to Audit and Monitor? Let the Protocol Risk Assessment Tool System Help You Prioritize

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1. Background

Clinical trials are a vital part of the development and approval of new medical treatments, but they also carry inherent risks to participants. To mitigate these risks, it is essential to ensure appropriate quality assurance oversight and selection of clinical trials for auditing and monitoring. Determining and prioritizing suitable studies to be audited and monitored can be difficult when the clinical trial portfolio of an institution is significantly large and complex. With the increasing number of clinical trials being conducted at Memorial Sloan Kettering Cancer Center (MSK), it is challenging for the MSK's Clinical Research Quality Assurance (CRQA) unit to prioritize and make decisions about the type, frequency, and extent of auditing and monitoring.

2. Goals

With a yearly average (2018-2022) of 230 active therapeutic institutional studies and 3,200 accruals, MSK's CRQA unit needed a strategic method to balance demand versus resource while ensuring appropriate quality assurance oversight.

3. Solutions and Methods

The MSK CRQA unit developed a scheme for defining, prioritizing, and assessing the risks associated with each therapeutic MSK-sponsored clinical trial by adopting a dual strategy. First, we use a Protocol Risk Assessment Tool (PRAT) to define the risks at the study level, using a simple risk categorization score for each key criterion (i.e., study phase, investigational new drug (IND) type, children risk level, etc.). Second, using PRAT scores and examining the trial design, population, and procedures, to identify specific areas of vulnerability, we can determine how risks can be mitigated via MSK's Audit and/or Monitoring Programs. PRAT is an in-house developed scoring system based on risk factors that have the potential to cause harm to participants. Each factor is assigned a score which in turn is used to calculate an overall CRQA Protocol Risk Score and assign a Protocol Risk Level (low, moderate, and high). The PRAT system is then able, in real-time, to automatically analyze large amounts of data and make recommendations for auditing or monitoring.

4. Outcomes

One of the key features of the PRAT system is its ability to handle large number of clinical trials and highlight studies that are most at risk. The PRAT system has helped CRQA navigate the growing list of clinical trials easily and efficiently by providing a user-friendly interface with advanced search and filtering capabilities. The system provides real-time alerts of new trials that are opened to accrual and meet CRQA's high-risk criteria.

5. Lessons Learned and Future Directions

The PRAT system has been tremendously useful to CRQA's workflow in identifying and managing studies for auditing and monitoring, and we look forward to further enhancements where real-time alerts can indicate recommendations to finalize monitoring activities based on specific timelines; real-time information on monitoring visit ratings; participant accruals; adverse event; and deviation reports. In summary, using a variety of data sources, advanced analytical techniques, and immediate updates, the

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PRAT system can identify high-risk trials and provide recommendations for auditing or monitoring. Additionally, it can handle large numbers of clinical trials, provide automated reports, and be integrated with existing systems, making it a powerful tool for risk assessment in clinical trials.