



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

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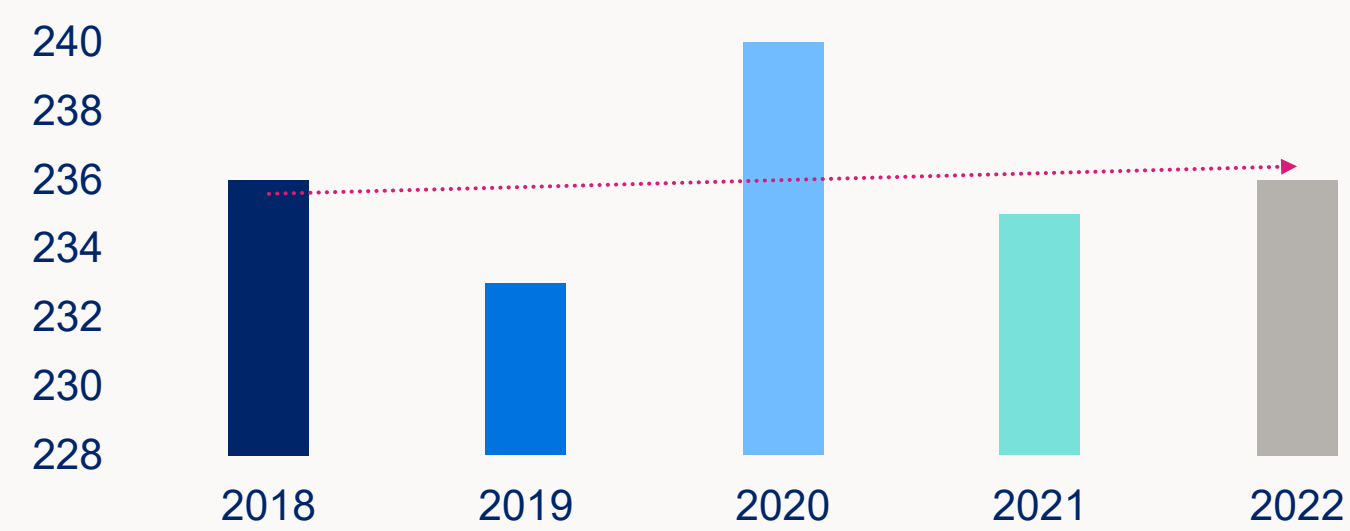
## BACKGROUND

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.

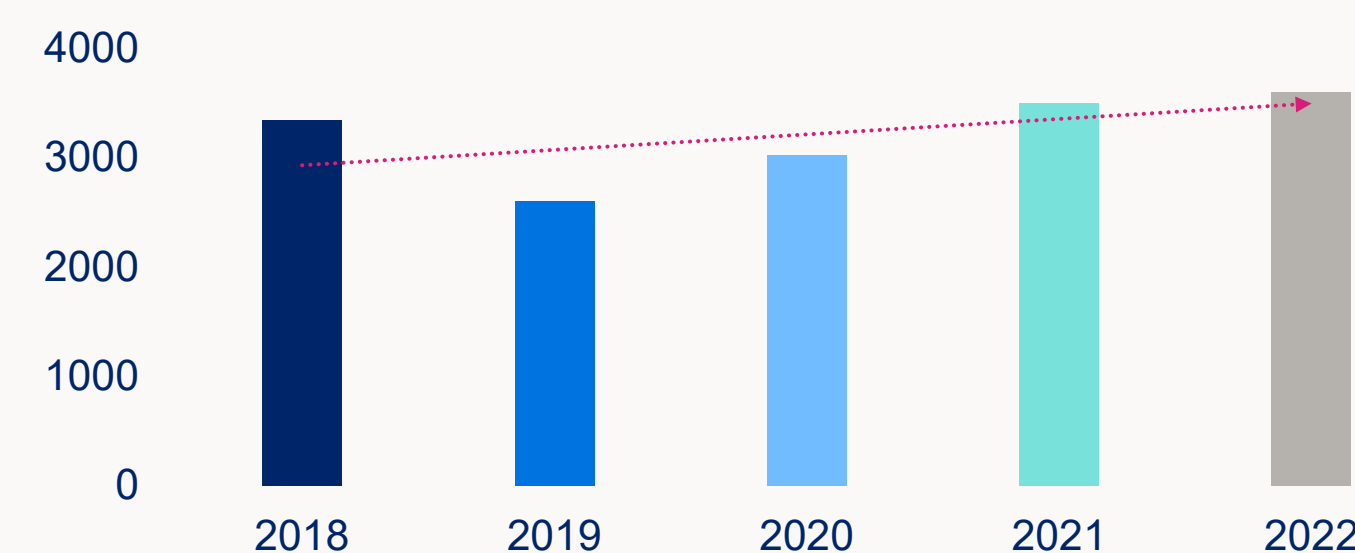
## GOALS

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

### Therapeutic MSK Sponsored Studies: Active



### Therapeutic MSK Sponsored Studies: Accruals



## METHODS

### DEFINE

MSK defined and assessed the risks of therapeutic MSK sponsored studies through the Protocol Risk Assessment Tool (PRAT), a CRQA-developed resource, using a risk categorization score calculated from predefined risk factors

### PRIORITIZE

MSK prioritizes studies with the highest risk scores and ensures a balanced distribution of quality assurance oversight across all clinical departments and services by selecting studies from each to be audited and/or monitored

### ASSESS

The PRAT system suggests which study should be audited or monitored (using a criteria based workflow). The Monitoring and Auditing Committee (MAAC) meet quarterly to review PRAT results and make final assignments/decisions

## RESULTS

The PRAT system analyzes 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 features. PRAT provides real-time alerts of new trials that are opened to accrual and meet CRQA's high risk criteria.

Audit trail in history view

Select studies to update or edit

RB Number	MSK Data Coordinating Center	Protocol Risk Level	DDO	Gene Therapy	IND Status	Risk Assessment Score	Previous Protocol Risk Assessment Score	Previous PRAT Score Date	Pending Workflow For	Protocol Assigned To	Date of Assignment to Monitoring	Date of Assignment to Audit	What is the Monitoring Review Status?	Date of Monitoring Completion?	What is the Audit Review Status?	Date of Audit Completion?	If Not Assign for CRQA Review, what is the Reason?	If 'Other' is selected, describe below	Record Status	Latest Cycle	MAAC Meeting Date	PIMS Decision
19-272	N/A	Moderate	NO	NO	Active	22	22	03/17/2023									High risk but no Capacity		Reviewed	March 2023	12/14/2022	Auditing
16-1405	N/A	Moderate	NO		Active	23	23	03/17/2023		Audit									Reviewed	March 2023	12/14/2022	Auditing
14-205	N/A	Moderate	NO		Pending	21	21	03/17/2023		Audit									Reviewed	March 2023	12/14/2022	Auditing
21-288	N/A	High	NO	NO	Active	26	26	03/17/2023									High risk but at the time of review the department/service being audited and/or monitored		Reviewed	March 2023	03/14/2023	Monitoring

Filter and search section

Result table, exportable to Excel

## CONCLUSION

The PRAT system has been a valuable tool for CRQA's workflow in identifying and managing studies for auditing and monitoring. During the first quarter of 2023, the PRAT system was further enhanced with alerts indicating recommendations to finalize monitoring activities based on specific timelines, real-time monitoring visit ratings, participant accruals, adverse events, and deviations. In summary, using a variety of data sources, advanced analytical techniques, and real-time data updates, the PRAT system can identify high-risk trials and provide recommendations for auditing or monitoring. Additionally, it can provide automated reports and be integrated with existing systems for additional data analysis, making it a powerful tool for risk assessment and risk mitigation for clinical trials.

## ACKNOWLEDGMENTS

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