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Streamlining PRMS Microprocesses: A Collaborative Guide to Reduce Study Activation Timelines and Increase Accrual by Prioritizing Review Assessments through Continual Monitoring

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1. Background

The Protocol Review and Monitoring System (PRMS) plays a critical role in ensuring the scientific integrity and regulatory compliance of clinical trials. In 2023, Simmons Comprehensive Cancer Center participated in the Performance Excellence and Quality Management (PExQM) project, a lean Six Sigma project initiative at the University of Texas Southwestern Medical Center in which the overall goal was to identify three to five focal tasks in 2024 for quality improvement. The project resulted in the PRMS streamlining submission and review processes between the Protocol Review and Monitoring Committee (PRMC), Human Research Protection Program (HRPP), feasibility committee, and disease-oriented teams (DOTs). Some of the key challenges discovered at the pre-submission phase for cancer-related trials from study submission to final PRMC approval included submission errors and inefficient tracking of stipulations which contributed to prolonged approval timelines.

To improve efficiency in these microprocesses, it is essential to implement continuous monitoring and more rigorous oversight to reduce submission errors, prioritize review assessments, and increase stakeholder knowledge of PRMS submission requirements and streamlined communication.

2. Goals

1. Provide DOTs with clear guidance to complete the submission process with minimal errors and to produce more compliant study submission packets.
2. Establish standardized procedures to expedite response to stipulations to reduce review to approval timelines.
3. Tighten the parallel review process between the PRMC and the institutional review board (IRB).
4. Utilize stakeholder meetings to monitor the study activation pipeline.
5. Report and give feedback through continuous monitoring of trials once activated to increase accrual progress.
6. Create training tools and resources submitters can use for cleaner submissions.
7. Decrease the need for repetitive review of trials by the PRMC and IRB.

3. Solutions and Methods

1. Revised electronic submission forms to decrease the number of incomplete forms submitted for PRMC review.
2. Hosted new staff training conducted specifically by the PRMC Sr. Program Coordinators via video conference and provided educational materials.
3. Developed review metrics for timelines related to the parallel processes for the PRMC and IRB.
4. Explored solutions for PRMC review of trials that can be fast tracked.
5. Modified Simmons Comprehensive Cancer Center protocol template to streamline scientific review of data and objectives.

4. Outcomes

The PRMS worked with the teams to establish uniform procedures to increase internal DOT communication and expedite response to stipulations to achieve faster time to PRMC approval. The

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PRMS enhanced the SharePoint site educational resources with links to self-help modules and reference material for study submissions. DOTs held study team meetings within three business days following PRMC meetings to complete stipulation responses in real time. A decrease in median time from PRMC submission to PRMC approval by two days overall.

5. Learned and Future Directions

The PRMS was able to modify current processes and identify additional processes needed to enhance expeditious review to decrease time to activation for high-priority clinical trials. The PRMS found that feedback to DOT leaders, investigators and study teams through interactive communication, training, and monthly accrual progress reports provided transparency and increased stakeholder engagement.