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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BACKGROUND

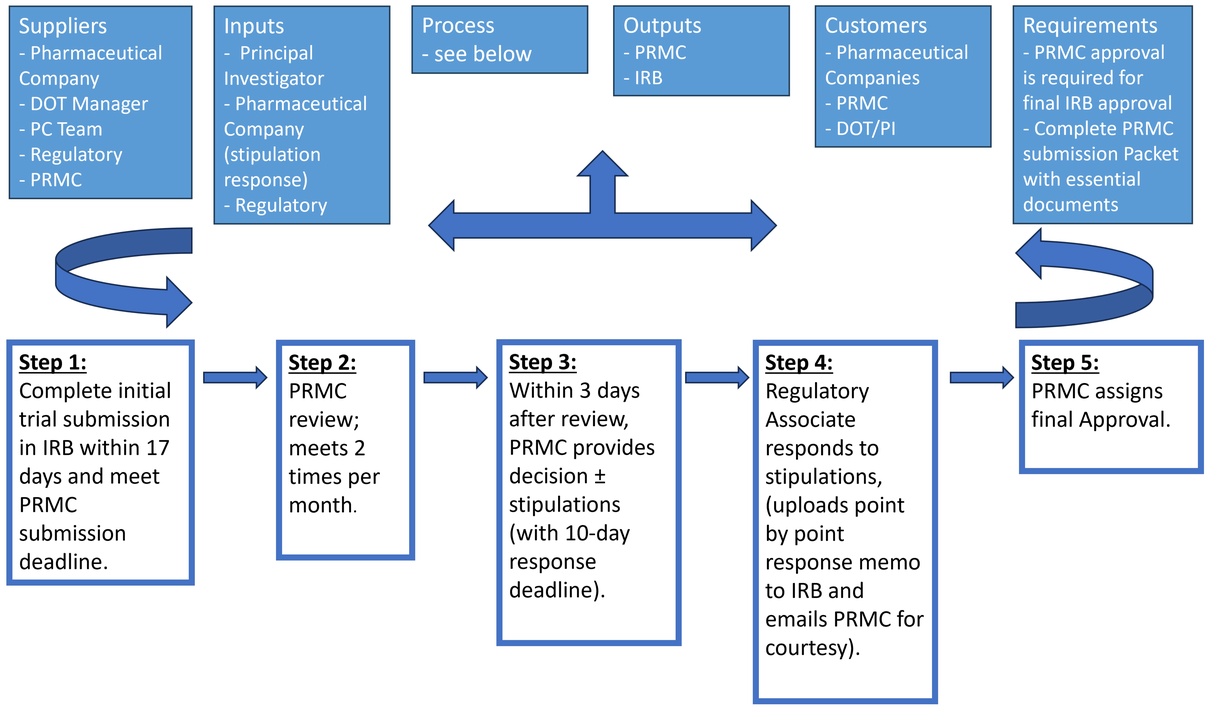
- The Protocol Review and Monitoring System (PRMS) plays a critical role in ensuring the scientific integrity and regulatory compliance of clinical trials.
- In 2023, SCCC participated in the Performance Excellence and Quality Management (PExQM) project, a lean Six Sigma project initiative at the University of Texas Southwestern Medical Center (UTSW) in which the overall goal was to identify focal tasks in 2024 for improvement.
- The project resulted in a streamlining of PRMS submission and review processes between the Protocol Review and Monitoring Committee (PRMC), Human Research Protection Program (HRPP), feasibility committee, and disease-oriented teams (DOTs).
- Key challenges discovered at pre-submission phase for 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 reduce submission errors, prioritize review assessments, and increase stakeholder knowledge of PRMS submission requirements.

GOALS

1. Provide DOTs with clear guidance to minimize errors and produce more compliant study submission packets.
2. Establish standardized procedures to expedite response to stipulations and reduce review to approval timelines.
3. Tighten parallel review processes between the PRMC and the IRB.
4. Utilize stakeholder meetings to monitor the study activation pipeline.
5. Continuous monitoring of trials once activated to increase accrual progress and provide regular feedback.
6. Create training tools and resources for cleaner submissions.
7. Decrease need for repetitive review of trials by the PRMC and IRB.

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.



OUTCOMES

1. The PRMS worked with teams to establish uniform procedures to increase internal DOT communication and expedite response to stipulations to achieve faster time to PRMC approval. A decrease in median time from PRMC submission to PRMC approval by 2 days overall.
2. The PRMS enhanced the SharePoint site educational resources with links to self-help modules and reference material for study submissions.
3. DOTs held study team meetings within 3 business days following PRMC meetings to complete stipulation responses in real time.

LESSONS LEARNED

- 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

FUTURE DIRECTIONS

- Will continue to collaborate with stakeholders to evaluate PRMS microprocesses, to develop best practices to expedite study submissions, reduce review timelines, and improve the overall time to study activation.
- Provide readily available educational resources and reference material.