

An Approach to Revitalizing PRMS Scientific Progress Reviews

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1. Background

National Cancer Institute (NCI) Cancer Center Support Grant (CCSG) Guidelines call for a mechanism for assuring adequate internal oversight of the scientific aspects of cancer trials. The Protocol Review and Monitoring System (PRMS) has the authority to terminate protocols that do not demonstrate scientific progress. Yale Cancer Center (YCC) PRMS had a process in place whereby demonstration of scientific progress was determined based upon biannual presentations by the Disease Aligned Research Team (DART). The DART Leader presented the portfolio to the Protocol Life Cycle Subcommittee (PLCS) of the Protocol Review Committee (PRC), a component of Yale's PRMS. It was logistically challenging to coordinate the presentation of 14 DARTs biannually. As a result, DART presentations were infrequent and evaluation of protocols was primarily based upon low accrual.

2. Goals

The goal was to develop a robust process for consistent reviews of scientific progress in an expedited and structured manner while minimizing the burden on the DART Leaders and PLCS members.

3. Solutions and Methods

PLCS staff developed and implemented a revised process for scientific progress reviews. PLCS evaluates the scientific progress of interventional trials that are open to accrual or temporarily suspended at the time of IRB renewal. Trials that are not scientifically relevant or will not meet their scientific objective(s) may be recommended to the PRC for closure.

We outlined the policy and procedures for scientific progress reviews, developed submission and reviewer forms and submission instructions. We utilized the ePRMS Console of Yale School of Medicine's Clinical Trials Management System, OnCore, for submission. We generated reports within OnCore to determine which studies are due for submission. We educated and trained the research teams, PRMS members and PRMS staff on the process, communicated with key stakeholders, and announced the implementation plan.

4. Outcomes

DART portfolio reviews were presented annually in 2015-2017 despite the expectation for biannual presentation. In 2016, three of 14 DARTs did not present and in 2018, 13 DARTs did not present their portfolios, which prompted suspension of portfolio reviews in Jun-2018. Since Oct-2019 when the new process was implemented, 13 of 14 DARTs have had individual protocols reviewed.

We do not yet have sufficient data to demonstrate the impact of the process on the rate of closure due to lack of scientific progress.

5. Lessons Learned

Category: Finance/CCSG/PRMS – Completed Project

We encountered studies where closure to accrual was imminent and a review of scientific progress was not necessary. Submitters communicate the expected closure date, provide supporting sponsor correspondence and review is waived.

We faced system limitations in the ePRMS console. Submitters cannot create another review of a different type when a review is in progress. To resolve, we withdrew the scientific progress report to allow submission of another type (i.e., an amendment), then resubmitted the scientific progress report when the other review is complete.

We have experienced delays in submission. PLCS members are determining how to handle late submissions and the appropriate action after sufficient follow-up attempts are made. We are considering using the IRB renewal report in lieu of a scientific progress report.