Category: Clinical Trial Operations – Completed Project

COVID Response: Providing Ongoing Oncology Clinical Research Support During a Pandemic

B. Oleson, J. Thomas, J. Bollmer, K. Schroeder, D. Pastorek, P. Jacobs, M. Pigsley, S. Zindars, G. Coly

Medical College of Wisconsin Cancer Center

1. Background

The first case of COVID-19 was discovered in the United States January 21, 2020. Less than two months later, the Medical College of Wisconsin (MCW) and adult Cancer Center Clinical Trials Office (CCCTO) transitioned to a mandatory work-from-home status for all non-essential staff. We had 261 patients receiving protocol interventional therapy at that moment. In the next month, 20 percent of our research team was furloughed. The most pressing issue was whether to suspend our research enterprise to new enrollment and focus only on current patients already under therapy or to allow select trials to remain open and additionally continue the new trial activation process.

2. Goals

Our goal was to develop criteria as to which trials should remain open for continuing enrollment and action on those in the activation process. At the same time, we needed to keep our patients and team safe while maintaining protocol compliance.

3. Solutions and Methods

The CCCTO leadership initiated the institutional discussions about clinical research management during the pandemic. Team managers completed a business continuity plan as requested by the MCW Office of Research, with our CTO medical director driving institutional decision making. The managers developed remote work responsibilities, communication plans, and workflows for their teams. Most trials were suspended, but MCW allowed a subset of cancer studies to remain open: trials where patients had no effective standard of care option (including some Phase I trials) or trials where the treatment intervention (e.g., hyperfractionated radiation therapy) required fewer on-site visits. The disease-oriented teams reviewed their portfolios using these criteria and identified studies to remain open, and the CTO medical director and administrative director then reviewed and approved the trial lists. Our institution developed a three-staged plan for trial reactivation, with the first phase beginning in May. We completed a document listing each trial's impact on services provided by hospital partners, e.g., likelihood of a subject needing ICU support or extended inpatient stay. We then submitted the CTO's reactivation proposal for institutional approval. The timing of each stage of reactivation was based on COVID related census and the capacity of our partner hospital to support the clinical research enrollment impact.

4. Outcomes

From 140 treatment trials available for enrollment on March 15, 2020, we dropped to a low of 42 by June 1. Through thoughtful reactivation and new trial activation, we reached pre-COVID levels of trial availability of 145 on November 16. Despite allowing only minimal staff presence on site and fewer on-site patient visits, we were able to offer treatment trial enrollment at a stable number (1.0 percent accrual increase compared to 2019).

Category: Clinical Trial Operations – Completed Project

5. Lessons Learned

Our approach to ongoing enrollment during the pandemic was a relative success. The measured approach to trial reactivation and increasing on-site staff support proved sufficient to maintain trial accrual. Continued robust accrual coupled with staff furloughs and offsite CTO staff did stress the available staff and led to delays in pending projects.