Category: Trial Start-up, Activation, Regulatory, and Protocol Development - Work in progress

Development of a Study Activation Grid to Track and Review Start-Up Activities

M. Jacklin, K. Schroeder, J. Bollmer

Medical College of Wisconsin Cancer Center

1. Background

The clinical trial activation process is very complex, with many activities happening in parallel. A need was identified to create a tool that increases visibility of these parallel processes, provides clear expectations and accountability for our clinical trials office departments and hospital partners, and reduces activation timelines.

2. Goals

- Develop a tool that highlights study start-up activities and lays out target dates for key steps in study activation
- Implement a defined, regular review process to track studies in activation
- Decrease overall study activation timelines

3. Solutions and Methods

In partnership with each of our clinical trials office departments (e.g., disease teams, regulatory, budget/contract), we have developed a standardized grid to track key milestones during study activation. The study activation grids highlight key submission dates and automatically project target dates for future tasks and submissions. The ultimate goal of the activation grid is to serve as a single, shared location where the study team can check the status of start-up activities in real time, and to help highlight bottlenecks in the process.

Along with the creation of the grid, we have implemented bi-weekly team meetings to review the status of each study and identify barriers to activation. These meetings include members of the clinical trials office operations team, regulatory team, budget and contract team, research managers, and hospital compliance office partners. Each department provides a progress update for all studies in activation during this meeting, with the goal of keeping all partners moving in the same direction towards the goal of timely study activation.

4. Outcomes

This tool, and associated bi-weekly review meetings, was implemented in August of 2023. Since then, we have activated 5 protocols using this process (1 industry, 3 national cooperative group, and 1 institutional). While this is a limited sample size, we have seen dramatic improvement in the activation times for studies that have gone through this review process. The single industry trial was activated in 158 days, where the institutional mean activation time in 2023 for industry trials was 280 days. The mean activation time for the 3 national trials opened through the grid review process was 80.7 days (institutional mean in 2023 was 128.6 days), and the institutional trial was activated in 195 days (institutional mean in 2023 was 250 days).

5. Lessons Learned and Future Directions

The implementation of a study activation grid and regular review meetings has so far successfully demonstrated a reduction in study activation timelines for the projects that have gone through the process. In addition to the data gathered so far, this process has increased general collaboration on study start-up activities within the clinical trials office and with our hospital partners. Frequent working

meetings provides the study team with needed accountability and visibility among all parties involved in study activation. We hope to continue to develop this process in partnership with MCW Cancer Center leaders and hospital partners to reduce activation timelines and ultimately bring more clinical trial options to our catchment area.