Category: Finance/CCSG/PRMS - Work in Progress

MSK's NCI Network Program

J. Mohr, L. Gaffney, C. Houston, M. Warren, C. Aghajanian, P. Sabbatini, E. Cottington, S. Ramaswami, B. Zakrzewski, J. Klinger, S. Dominguez, S. Terzulli, J. Nunner, A. Rodavitch, K.R. Simpson, S. Hanley

Memorial Sloan Kettering Cancer Center

1. Background

As an NCI-Designated Comprehensive Cancer Center, Memorial Sloan Kettering (MSK) receives funding via the Cancer Center Support Grant (CCSG) which requires collaboration in National Cancer Institute (NCI) research efforts. MSK does this largely though participation in and enrollment to NCI-sponsored group studies. As part of the CCSG renewal process, MSK examined our NCI-sponsored group portfolio and noted siloed physician leadership, quality concerns, and limited financial support.

2. Goals

MSK formed a central team of NCI experts to manage regulatory compliance, create a nimble protocol activation process, improve audit results, and initiate institutional cost sharing to ensure sufficient funding of clinical trials and to determine the true cost of these trials.

3. Solutions and Methods

The NCI Network Committee was established and consists of grant and NCI group principal investigators (PIs) in addition to disease specific champions. Members meet monthly to review protocols in the activation process, accrual metrics, non-performing studies and grant and data metrics. NCI subject matter experts were centralized and make up the NCI Network Team. They have three areas of focus: protocol activation, operations/regulatory management, and quality assurance. They provide oversight and support to all MSK PIs and study teams participating in NCI Group protocols. To streamline activation, the NCI Network team developed a workflow to solicit timely decisions by MSK PIs on which trials to activate. Decisions and timing metrics are kept in a REDCap database. Select operations and regulatory tasks were centralized, allowing more time for data entry and patient management by the study teams. Quality assurance measures were implemented including risk-based monitoring (RBM) on a subset of trials, an escalation plan for trials with data timeliness concerns, and 100 percent retrospective source verification for eligibility and informed consent. In addition, we track activation, data entry, and regulatory metrics to evaluate the progress of our program. To address the limited funding for these clinical trials, it was determined by MSK that they would cost-share the clinical trial expenses related to these trials as opposed to requiring the MSK PI to identify supplemental funding. The centralized team is supported by grant funding and each clinical trial is supported by the pre-determined annual amount per grant. Once the annual amount identified per grant is exhausted, the clinical trial expenses transition to the applicable cost share fund.

4. Outcomes

Compared to pre-centralization data, we've improved data reporting timeliness while increasing our portfolio (Figure 1). We have also reduced the time from NCI approval to MSK confirming they want to open the trial to activation at MSK and in 2021 we are going to see further improvement with new workflows that further streamline the activation process.

Category: Finance/CCSG/PRMS - Work in Progress

5. Lessons Learned

This program is necessary for ensuring the focus, direction and efficient use of institutional resources. In a survey of site PIs, 70 percent indicated they were extremely satisfied with the program. Future plans:

- Utilize REDCap database to monitor new activation process and aid grant reporting
- Expand RBM to occur after initial subject enrollment to identify and correct issues early on
- Build on current program to increase PI satisfaction

Figure: