Category: Finance/CCSG/PRMS – Work In Progress

Memorial Sloan-Kettering's Protocol Review Core: A Specialized Approach to Protocol Review Committee Management

S. Hanley, J. Migliacci, C. Ryan, X. Lekperic, K. Napolitano, A. Rodavitch

Memorial Sloan Kettering Cancer Center

1. Background

Prior to 2018, Memorial Sloan Kettering Cancer Center's (MSK) pre and post-activation protocol review system was fragmented. Each departmental and institutional regulatory group had independent staff and unique leadership and processes to manage their review committees. Committees were siloed with little communication between groups, causing unclear review scope and inefficiencies for both new reviews and monitoring of protocols. This was further complicated by MSK's large research portfolio with 800+ active prospective protocols and 1200+ retrospective and biospecimen clinical research studies; 552 total protocols entered the review & activation process in 2019.

2. Goals

To improve overall institutional protocol review process, MSK's major goals were to:

- Create a specialized team to manage complex review processes throughout protocol lifecycle
- Standardize pre- and post-activation reviews while simultaneously customizing best practices based on individual committee needs
- Provide high-level customer service to enhance varied users' experiences
- Decrease Time to Activation (TTA) and Time to IRB Approval (TTIA), defined as the number of days from the first review to when a protocol is open for patient enrollment and IRB approval, respectively.

3. Solutions and Methods

In 2017, the Protocol Review Core (PRC) was created to manage all non-IRB protocol reviews at MSK. This specialized team of 10 full-time employees is responsible for managing 29 departmental and institutional committees. PRC committees review new protocols, amendments, regulatory submissions, and conduct accrual and data and safety monitoring. PRC has developed best practices for protocol review and monitoring committee management which includes:

- Defined scope through committee review letters and reviewer checklists
- Standardized routine reporting of metrics to inform committees on effectiveness, progress and volume
- Active PRC participation in all aspects of protocol reviews
- Increased transparency and communication across committees
- Expanded review space to include feasibility committees for multi-site and regional site participation
- Leveraging home-grown technology for data capture and tracking to benefit the research community

- Customized review requirements and monitoring criteria, including varied review flows and flexible deadlines
- Standardized administrative approach for all protocols entering review process to provide comprehensive information for committee reviews and allow for cross coverage

4. Outcomes

PRC's integration into MSK's protocol review process has resulted in a standardized approach to protocol reviews while simultaneously increasing efficiencies and enhancing the user experience. This centralized structure has resulted in:

- PRC actively managing the review of protocols from initial review to study closure
- Decrease in institution's median TTA, TTIA, and departmental time to approval (DTTA) for all protocol types from 2017 to 2019
    - TTA: 177 to 137
    - TTIA: 132 to 86
    - DTTA
        - Industry: 32 to 17
        - IIT: 64 to 49
        - NCI: 37 to 22

5. Lessons Learned

Lessons Learned:

- PRC is an essential component of optimizing the protocol review process at MSK
- Customizing our approach has enhanced our engagement of previously siloed, independently managed groups
- Formalized best practices support PRC's mission in quality and efficient protocol reviews

Future Directions:

- Define/triage high priority, complicated, unique protocols
- Broaden scope of feasibility committees to capture additional groups (e.g. information technology, infection control)
- Data visualization technology
- Standard Operating Procedures to share with external groups