Category: Trial Start-up and Activation - Completed Project

Strategies to Expedite Activation of Expanded Access Protocols at Memorial Sloan Kettering Cancer Center

X. Lekperic, E. Valentino, S. Hanley, A. Rodavitch

Memorial Sloan Kettering Cancer Center

1. Background

An NCI-Designated Comprehensive Cancer Center, Memorial Sloan Kettering (MSK) has over 1,000 clinical trials and expanded access protocols (EAP). EAPs provide access to pre-approval, investigational drugs outside of a clinical trial and patients who rely on them often have no other similar or acceptable therapeutic options available. It is essential to review and activate EAPs efficiently so patients can have access to treatment as soon as possible. MSK's Protocol Review Core (PRC) and Protocol Activation Core (PAC) identified roadblocks in reviewing and activating EAPs and established a working group to improve our processes.

2. Goals

- Create an institutional EAP review and activation workflow
- Decrease EAP Time to IRB Approval (TTIA) [time from primary department submission to IRB approval] and Time to Activation (TTA) [time from primary department submission to activation]

3. Solutions and Methods

The working group first streamlined the institutional definition of an EAP to include any protocol with a primary objective of providing access to a treatment or device with no scientific endpoints. We then conducted a pilot, met with various groups (finance, legal, pharmacy, etc.), and finally implemented a new review and activation workflow comprised of:

- Lean administrative pre-review process
- Expedited, concurrent pre-IRB reviews to eliminate bottlenecks
- Streamlined and focused committee reviews
- Administrative protocol review and monitoring system (PRMS) reviews focused on resources and prioritization
- Enhanced internal communication between PAC and PRC and use of shared tools such as:
    - Trello boards
    - Internal protocol information management system (PIMS)
    - Protocol tracker
- Condensed activation process
    - ICF drafted early (within 3 days of primary department submission)
    - CTMS calendar request, budget, contract flagged as high priority to expedite calendar build and external negotiation timelines (if applicable)
    - Flexibility with the internal start-up tools required to open to accrual (e.g., protocol order sets and CTMS calendar completion)

4. Outcomes

The new EAP review and activation workflows have improved communication and transparency between PAC/PRC and the greater MSK research community, sponsors, and CROs.

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When comparing 7 EAPs pre-EAP pilot versus 7 EAPs in the pilot, there were significant improvements in our various review and activation metrics such as:

- 58 percent decrease in time from primary department submission to PRMS approval (12 to 5 median days)
- 35 percent decrease in time from primary department submission to IRB approval (26 to 17 median days)
- 18 percent decrease in TTIA (51 to 42 median days)
- 24 percent decrease in TTA (81 to 62 days)
- 33 percent decrease in difference between TTA and TTIA (30 to 20 median days)

5. Lessons Learned and Future Directions

Lessons Learned:

- Protocol review and activation efficiency is only as good as the communication between teams
- Defining scope of reviews ensures efficiency of protocol review committees
- Activation workflows must consider and involve external teams (e.g., budgets, contracts, etc.)
- Investigator Initiated Trials take longer and must be considered separately from externally sponsored protocols

Future Directions:

- Further decrease time from primary department submission to IRB submission
- Further decrease TTIA, TTA, and the difference between them so that patients can access treatment quickly post-IRB approval
- Use EAP workflow experience to identify and eliminate bottlenecks in other types of protocol reviews

Figure: