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

Xhenete Lekperic, Sara Hanley, MSW, Emily Valentino, MPH, Ann Rodavitch, MA

Background

- An NCI-Designated Comprehensive Cancer Center, Memorial Sloan Kettering (MSK) has over 2,000 active 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.

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]

Methods & Solutions

Working group was created, and first task was to streamline institutional definition of EAP: *any protocol with a primary objective of providing access to a treatment or device with no scientific endpoints.*

Conducted 16-week pilot of 7 protocols. Pilot included PRC and PAC meetings with research operations, legal, finance, information technology, and pharmacy teams to streamline workflow details.

Presented workflow proposal and pilot data to all stakeholders then Center leadership. Then, implemented new review and activation workflow and trained PRC and PAC staff.

New review & activation workflow includes:

- Lean, administrative pre-review process so protocols can expeditiously begin review & activation process
- New EAP Review Flow (Figure 1) with expedited, concurrent, streamlined, and focused pre-IRB reviews to eliminate bottlenecks
- Administrative Research Council (RC) reviews focused on resources and prioritization. RC is MSK's Protocol Review and Monitoring System (PRMS).
- Enhanced internal communication between PAC and PRC including shared tools such as EAP identification workflow (Figure 2), Trello Board for tracking activation tracks, Internal Protocol Information Management System (PIMS), and protocol trackers.
- Condensed activation process including early informed consent form creation (within 3 days of starting review process), expedited CTMS calendar build, budget finalization, and contract execution (all flagged as high priority by PAC). There is also flexibility with internal start-up tools required to Open to Accrual such as protocol order sets and CTMS calendar completion.

Figure 1:
Externally Sponsored Expanded Access Protocol Review Flow

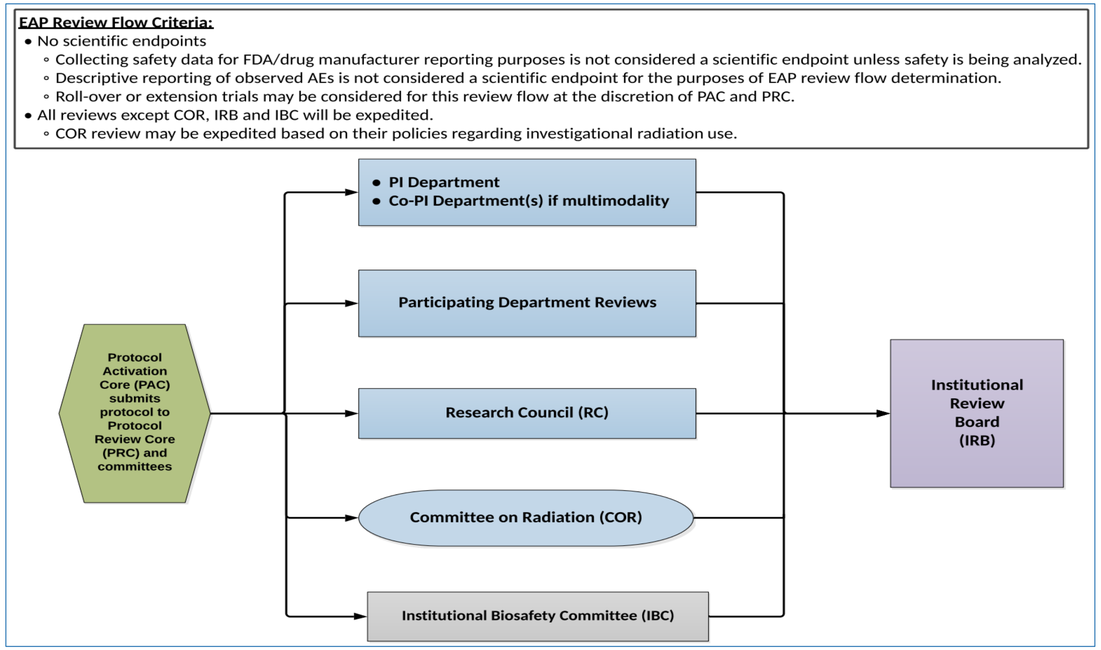


Figure 2:
Expanded Access Protocol Identification Workflow

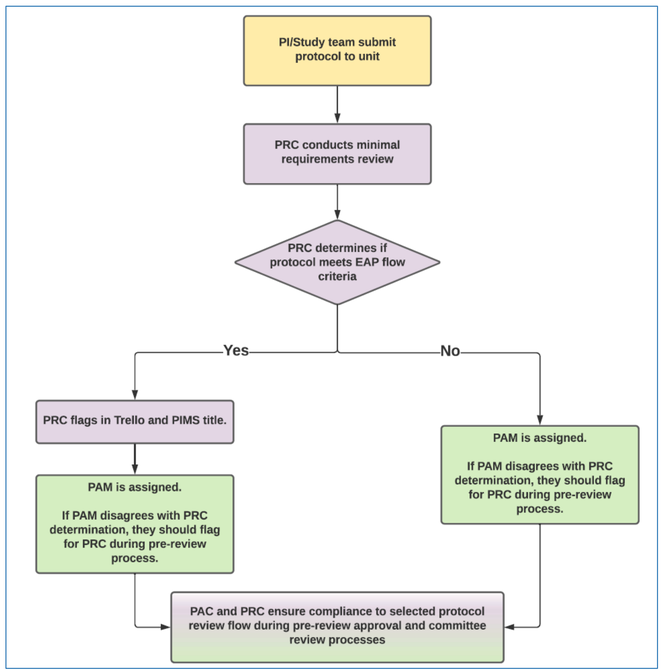
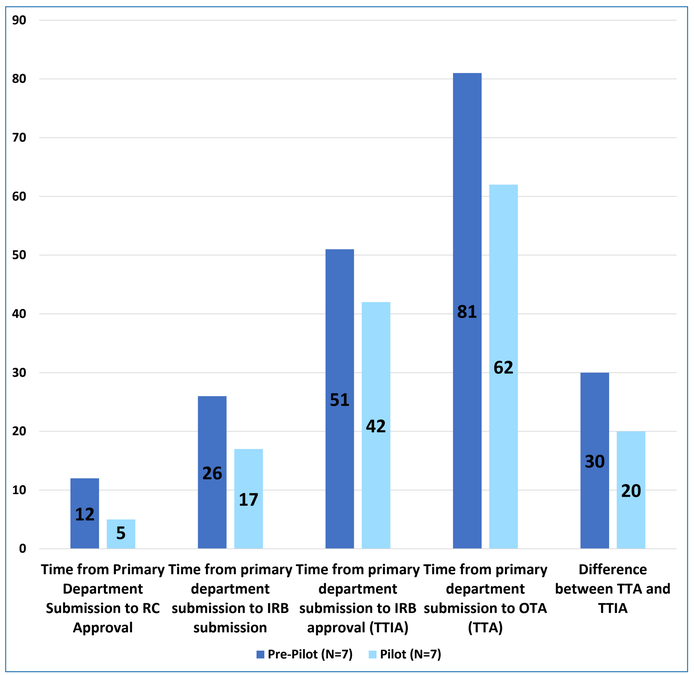


Figure 3:
Expanded Access Workflow Review & Activation Metrics Impact



Outcomes

Improved communication and transparency:

- Enhanced communication between PRC/PAC
- Transparency and enhanced collaboration with study teams, sponsors, and CROs

Improved submission & review metrics:

- 58% decrease in Time from primary department submission to RC approval (12 to 5 median days)
- 35% decrease in Time from primary department submission to IRB approval (26 to 17 median days)

Improved activation metrics:

- 18% decrease in TTIA (51 to 42 median days)
- 24% decrease in TTA (81 to 62 days)
- 33% decrease in difference between TTA and TTIA (30 to 20 median days

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