Category: Trial Start-up, Activation, and Protocol Development – Work in Progress

Evolution of MSK's Protocol Activation Core

J. Migliacci, M. Kehoe, E. Valentino, A. Rodavitch

Memorial Sloan Kettering Cancer Center

1. Background

Memorial Sloan Kettering Cancer Center (MSK) has a high volume of protocols in activation, opening an average of 36 prospective, retrospective, and biospecimen protocols each month. Prior to 2018, protocol activation was managed locally by the principal investigators' (PI) research teams without central oversight of study start-up. MSK identified that activation processes were inefficient and launched the Protocol Activation, Review and Human Research Protection Program centralizing activation and review committee management.

2. Goals

Since our centralized unit included oversight of protocol review committees, it allowed us to seamlessly coordinate protocol review and approval. However, due to the complexity of protocol activation, the Protocol Activation Core (PAC) was tasked with centralizing and streaming other study start-up activities ensuring that all required tools were ready, and tasks were completed at the time of activation so that we can enroll patients to new treatments quickly.

3. Solutions and Methods

PAC has evolved gradually over the last five years. Figure 1.A. illustrates the expansion timeline and added responsibilities. PAC was tasked with facilitating communication between the PI, local study team, and all other key stakeholders in activation, including the sponsor, finance, legal, etc., ensuring that all requirements were fulfilled before opening a study to enroll patients. By the end of 2018, our PAC team included 12 staff members.

In 2020, PAC responsibilities expanded to include creation of key operational tools known to delay activation (i.e., protocol order sets and eligibility checklists). During this time, senior managers were aligned to research departments to provide a "concierge" experience for all PIs participating in study star- up. The additional responsibilities resulted in expanding the team further, with 24 new staff.

In 2022 our team began an "expansion pilot" for five research departments, taking on almost all remaining non-logistical activation activities (e.g., billing harmonization, SIV preparation and facilitation, regulatory document collection, etc.), which resulted in the addition of 17 new staff. While preparing for the pilot, we extensively evaluated the processes of the pilot tasks and focused significant effort to streamline tasks before the rollout, including identification of improvements and system enhancements to reduce task completion time and ensure these tasks were not delaying activation.

4. Outcomes

Forty-seven prospective studies have started activation in the expansion pilot, of which 17 studies have been activated to enroll participants. When comparing activated pilot studies to activated non-pilot studies (N=278) that started activation in the same timeframe, we have seen an improvement at all stages of activation (Figure 1.B). The most notable change was in the stage between IRB approval and open to enrollment (waiting to open) with a 44 percent decrease in median days.

5. Lessons Learned and Future Directions

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We plan to gradually add research departments to the pilot throughout 2023 preparing for a full rollout in 2024. The pilot has allowed us to assess the size of the team adequately and ensure we're "right-sized" for the complete rollout. We have been and will continue to identify improvements to streamline our workflows and evaluate our activation metrics to ensure that we're continuing to reduce the time it takes to open studies.

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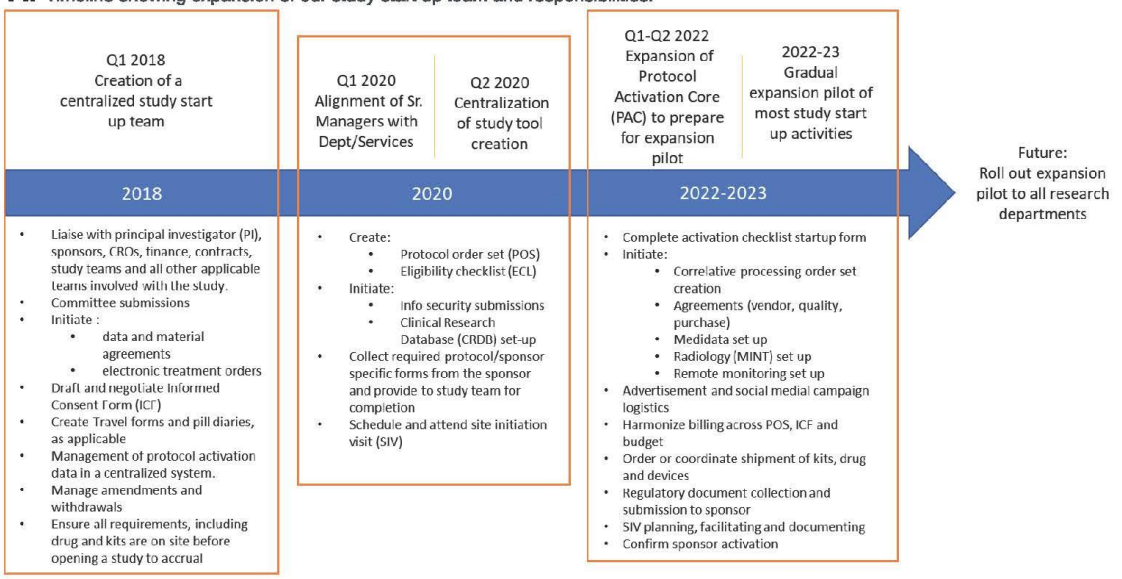
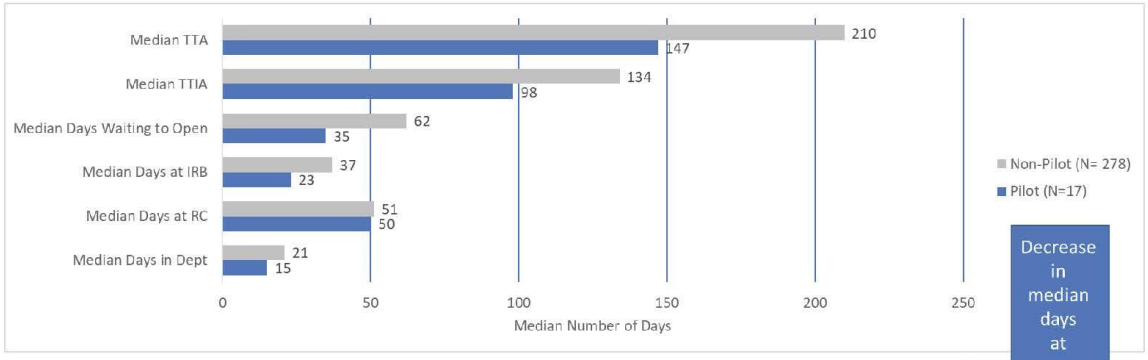
Figure 1

A. Timeline showing expansion of our study start up team and responsibilities.



B. Graphical depiction of the decrease in median days at all stages in activation, most motably was the 44% decrease in days between IRB approval and open to enrollment (waiting to open). Each stage is shown as a clustered bar graph. Dept is our disease specific review. RC is our scientific review committee. IRB is our institutional review board, Waiting to open is the number of days between IRB approval and date open to patient enrollment. TTIA is time to IRB approval defined from submission to primary department (dept) to IRB approval. TTA is Time to Activation, defined from submission to priamry dept to activation of a study for patient accrual.



% Change	Dept	RC	IRB	Waiting to Open	TTIA	TTA
	-29%	-2%	-38%	-44%	-27%	-30%