Evolution of MSK's Protocol Activation Core

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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 (HRPP) centralizing activation and review committee management.

Goals

- Our initial centralized unit, which included oversight of protocol review committees and HRPP, allowed us to seamlessly coordinate protocol review and approval; however, the Protocol Activation Core (PAC) was only responsible for only a portion of all activation activities (shown in Figure 1).
- Due to the complexity of protocol activation, PAC was tasked with gradually streamlining and expanding the number of centralized activities, ensuring tasks were completed at the time of activation so that we can enroll patients to new treatments quickly.

Methods

- 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 start up. requirements were fulfilled before opening a study to enroll patients.
- Over ~5 years, PAC gradually centralized most activation activities (Figure 1) which resulted in our team's expansion (Figure 2).
- We have extensively evaluated the processes of tasks and focused significant effort to streamline processes, including identification of improvements and system enhancements to reduce task completion time and ensure these tasks were not delaying activation.

Figure 1. Expansion of Protocol Activation Responsibilities over ~5 years

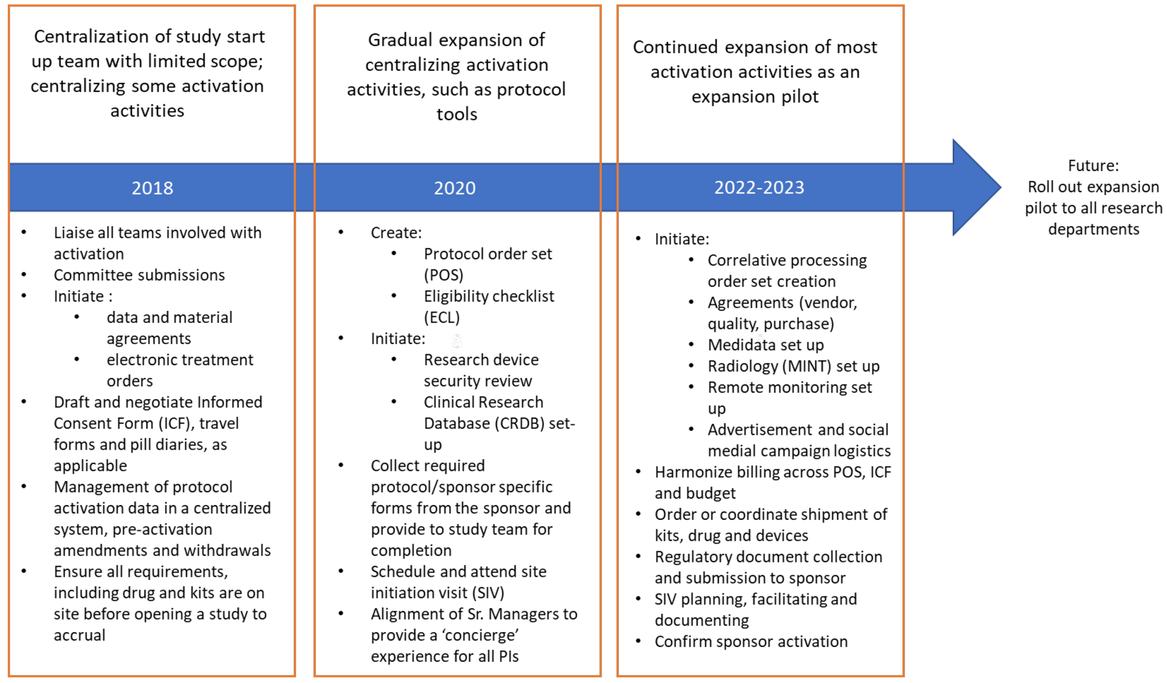


Figure 2. Staffing Expansion over ~ 5 years

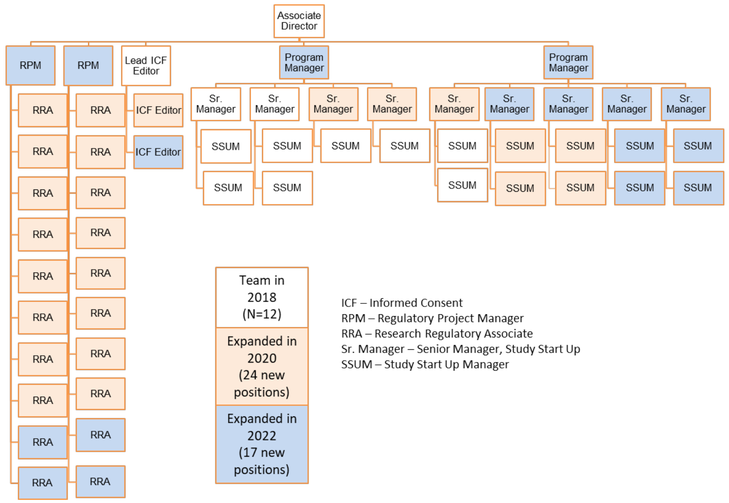
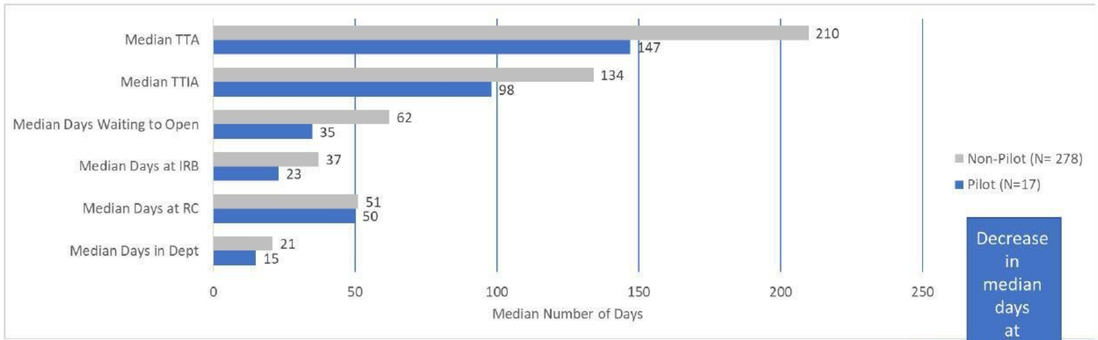


Figure 3. Graphical Depiction of Changes in Medians*



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

*includes all types of protocols (i.e., investigator initiated, industry, mission critical, etc.)

Outcome

- 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 3).
- The most notable change was in the stage between IRB approval and open to enrollment (waiting to open) with a 44% decrease in median days.

Lessons Learn and Future

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