

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. Ex

Centralization of st up team with limit centralizing some activities

2018

- Liaise all teams inv activation
- Committee submis Initiate
- data and m agreement
 - electronic orders
- Draft and negotiate Consent Form (ICF forms and pill diar applicable
- Management of pr activation data in system, pre-activat amendments and
- Ensure all requirer including drug and site before openin accrual

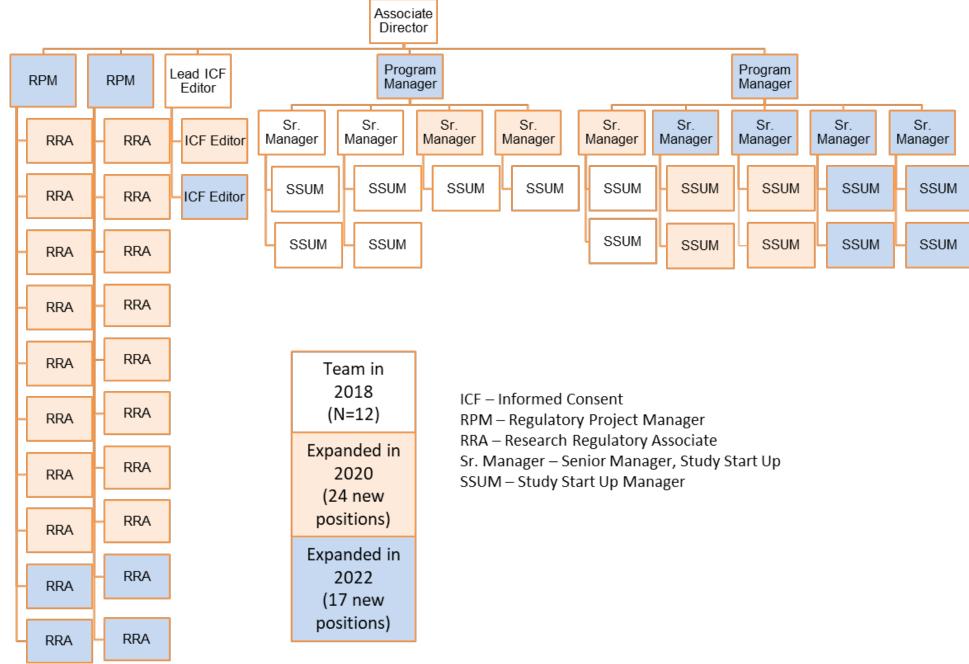


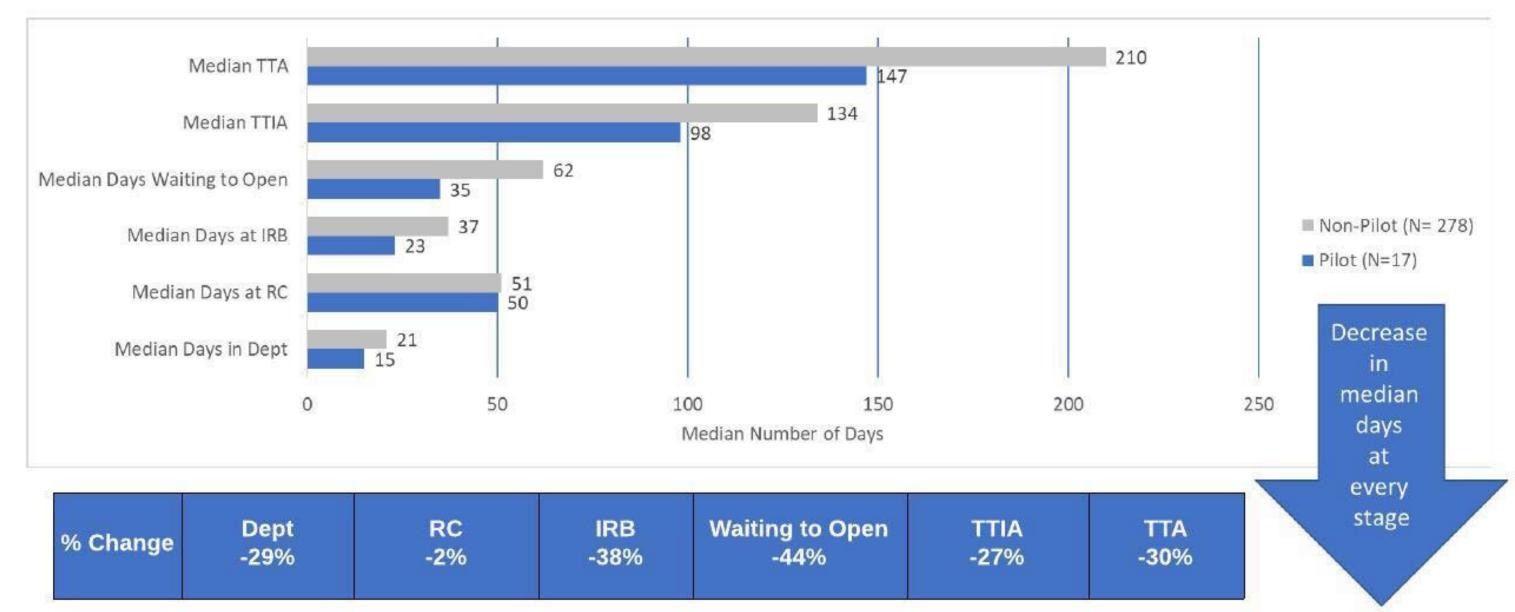
Figure 2. Staffing Expansion over ~ 5 years

Evolution of MSK's Protocol Activation Core

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Expansion	of Protocol Activation Re	sponsibilities over ~5 yea	ars	Outcome
f study start nited scope; e activation es	Gradual expansion of centralizing activation activities, such as protocol tools	Continued expansion of most activation activities as an expansion pilot	Future: Roll out expansion plot to all research departments	 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
3	2020	2022-2023		
involved with missions material ents ic treatment iate Informed CF), travel aries, as protocol n a centralized vation d withdrawals rements, nd kits are on ing a study to	 Create: Protocol order set (POS) Eligibility checklist (ECL) Initiate: Research device security review Clinical Research Database (CRDB) set- up Collect required protocol/sponsor specific forms from the sponsor and provide to study team for completion Schedule and attend site initiation visit (SIV) Alignment of Sr. Managers to provide a 'concierge' experience for all Pls	 Initiate: Correlative processing order set creation Agreements (vendor, quality, purchase) Medidata set up Radiology (MINT) set up Remote monitoring set up Advertisement and social medial campaign logistics Harmonize billing across POS, ICF and budget Order or coordinate shipment of kits, drug and devices Regulatory document collection and submission to sponsor SIV planning, facilitating and documenting Confirm sponsor activation 		

Figure 3. Graphical Depiction of Changes in Medians*



studies.

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