Performance Based Web Application Accelerates Clinical Trial Activation in Pilot Study

Therica Miller MBA, Sheilah Hurley MA, Mahendra Yatawara MBA, Rebecca Flores-Stella BS CIP, Keren Dunn BA CIP, Ryan Schroeder BA, Haibin Wang PhD, Shao-Chi Huang BS, Kevin Dudley BA, Robert Figlin MD, Monica Mita MD, Christine Szekely PhD, Howard Sandler MD MS, Steven Piantadosi MD PhD

BACKGROUND

Academic sites are continuously challenged to improve trial activation timelines however required committee reviews, regulatory approvals, contracting, and budgeting are often conducted serially and without a method of monitoring deliverables, accountability, or optimizing performance resulting in unpredictable and usually lengthy trial activation times.

METHODS

A Rapid Activation (RA) committee comprised of leadership and senior management redesigned the institutional trial activation workflow with a goal to open early phase oncology trials in 42 days. Historical procedures were replaced rather than scrutinized and key milestones identified. Six test trials were activated in succession over one year. Workflow improvements were made after each activation. Specifically, non-value added steps were eliminated, parallel processing was implemented, and ad-hoc committees were established. Target deadlines were set for each critical task and timelines were recorded and monitored *(Figure 1)*. After testing the RA workflow, a web-based collaborative workflow tracking tool (PRAT) was created to provide a simple visual interface for key stakeholders to monitor each trial through the process to avoid bottlenecking, measure performance, and to increase accountability *(Figure 2)*. Recognizing industry partner engagement was crucial, at RA6, target completion times were shared and sponsor commitment to turnaround times for each critical task was secured.

Figure 1

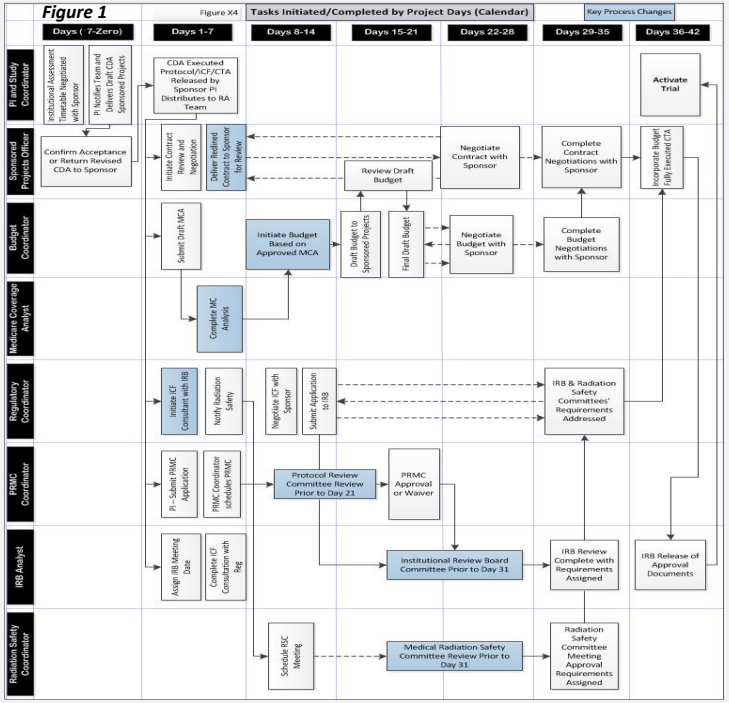
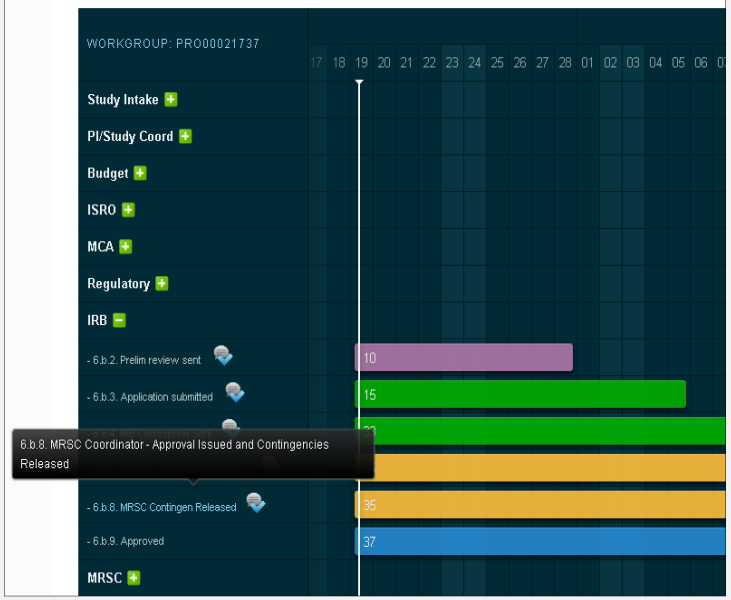


Figure 2 Timetable Key: Not Started | In Progress | Completed On Time | Completed Late | Incomplete



RESULTS

Cancer clinical trial activation times were reduced significantly from the standard of approximately six months. Activation times are shown in Table 1. Times in excess of 42 days were largely due to sponsor delays; the outliers were contracting and budgeting.

Table 1 **Rapid Activation of Early Phase Trials**

KEY ACTIVITIES	DAYS TO COMPLETION					
	Trial 1	Trial 2	Trial 3	Trial 4	Trial 5	Trial 6
CRO Regulatory: IRB Preparation	37	29	20	14	15	10
IRB Processing	43	42	9	18	46	25
MCA Processing	16	16	20	19	13	4
Scientific (PRMC) Committee Review	30	35	30	22	22	5
Radiation Safety (MRSC) Committee Review	21	72*	48	36	60	25
Budget Negotiated	21	43	37	36	50	12
Contract Executed	43	54	78	53	59	31
Trial Activation	**49**	**54**	**78**	**58**	**62**	**32**

** This includes MRSC review of both Phase 1a and 1b. Phase 1b was not included in trial activation time.*

CONCLUSION

Considerable effort is required to significantly alter the complex clinical trial activation workflow. Appropriate priorities, leadership, resources, and tools are required. The next phase of this project will be to study the feasibility of expanding rapid activation to a larger portfolio of clinical trials. Utilizing the PRAT system, activation data will be collected for all hematology / oncology trials processed in an upcoming 12 month time period. These data may be used to develop processes and modify staffing to expand RA procedures and timelines to a larger number of protocols. We will also measure sponsor interactions and other dependent processing times. Through this assessment and workflow improvement it is anticipated that the beneficial results seen through RA can positively impact timelines across all oncology trials at this institution.