Clinical Research Coordinator Workload Estimation and Tracking

M. Repede, D. Beighley, K. Putz, A. Fritsche, G. Nowakowski

Mayo Clinic Cancer Center

1. Background
The Mayo Clinic Cancer Center clinical research office (CRO) in Rochester, MN employs about 90 clinical research coordinator (CRC) staff to support over 600 active studies including Phase I, II, and III clinical trials. Annually, about 250 trials are proposed for consideration and planning.

Historically, CRO supervisors utilized various tools to manage staffing. Estimating required effort for a trial involved exhaustive review of all support tasks. Conversely, staffing assignments relied on supervisor experience and intuition. Given the CRO's current scale and complexity, a better system was required to align CRC staffing to trial support workload.

2. Goals
The team sought to implement a comprehensive and integrated staffing to workload system. This was broken into three phases, each to be rolled out successively:
- Estimate CRC workload required to support a given study
- Track CRC staffing assignments and actual workload
- Align staffing to workload

3. Solutions and Methods
Two of the above goals have been realized.

First, a sizing tool was developed to estimate the CRC effort required to support a given trial. Based on the study protocol, a supervisor considers four study aspects (screening, active treatment, follow-up treatment, visits) and inputs several numeric values, including the number of trial participants and complexity (on a 1-7 scale) for various tasks. The tool then outputs required effort in per-study, per-patient, and per-visit units.

Next, a tracking tool was created for CRC staff to record the number of patients and visits they supported for each trial. Combined with effort values output from the sizing tool, total monthly efforts are calculated and used for monthly effort certification.

4. Outcomes
Five experienced individuals estimated eight studies utilizing two approaches: the exhaustive line-item tool, and the new sizing tool. The resulting effort estimates were, on average, within 5 percent of each other which confirmed the accuracy of the new tool. The line-item tool took 2-6 hours (depending on protocol complexity), compared to 10-45 minutes with the new tool. This time savings of 85-90 percent demonstrated significant improvement. Aggregated across 250 estimates per year, this saves the team eight person-months annually.

Ninety CRC staff piloted the tracking tool for three months. Compared to the previous system of logging daily how they spent their time, the new tracking tool reduced complexity by instead tracking patients and visits supported. This resulted in time 5-10 minutes saved per person, per day. Aggregated across the team, this is a savings of over 150 hours each month.

5. Lessons Learned and Future Directions

Introducing easy-to-use tools that reduce administrative burden has improved job satisfaction for supervisors creating estimates and CRCs tracking their work. Managers also value objective measures of the team's workload and feel more confident in their staffing decisions. Finally, investigators appreciate rapid estimate turnaround on trials they propose.

Opportunities to improve the existing system include refining workload estimates to better reflect post COVID-19 workflows and expanding the IT infrastructure to support backups and concurrent usage. The primary focus, though, is addressing the third goal of surfacing insights about staffing assignments and team capacity to enable supervisors and managers to effectively align staffing to workload.

Figure:

Trial #	Calculated CRC Effort Estimate (hours)		Difference
	Line-Item Tool	**New Sizing Tool**	
1	3,408	3,375	-1.0%
2	12,316	12,330	0.1%
3	685	670	-2.2%
4	5,280	5,313	0.6%
5	2,705	2,835	4.8%
6	2,315	2,404	3.8%
7	3,305	3,225	-2.4%
*8	2,795	3,361	20.3%
			2.1%
*The PI for this trial stated that the new sizing tool better reflected the amount of CRC support required.			