Clinical Research Coordinator Workload Estimation and Tracking

Michael Repede, Dawn Beighley, M.S., Kimberly Putz, Angela Fritsche, M.P.A., Grzegorz Nowakowski, M.D.
Mayo Clinic Cancer Center

ABSTRACT

BACKGROUND
The Mayo Clinic Cancer Center Clinical Research Office (CRO) in Rochester, MN employs about 90 Clinical Research Coordinator (CRC) staff to support 600+ active studies including Phase I, II, and III clinical trials. Annually, about 250 trials are proposed for consideration and planning.

OBJECTIVE
Historically, CRO supervisors used various tools to manage staffing. Estimating the 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.

METHODS
A comprehensive and integrated staffing to workload system was broken into 3 phases, each to be rolled out successively:

1. **Sizing Tool:** Estimates CRC workload required to support a given study.
2. **Tracking Tool:** Monitors CRC staffing assignments and actual workload.
3. **Management Tool:** Aligns staffing to workload.

RESULTS
The first two phases are complete. Tooling has been validated, refined, and adopted by the team to size the workload for, and track the effort on, each trial.

CONCLUSION
CRC staff, supervisors, managers, and investigators all benefit from tools that produce results quickly and easily.

SOLUTIONS AND METHODS

Two of the project phases have been realized:

- 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.
- A Tracking Tool was also 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.

SIZING TOOL RESULTS

5 experienced individuals estimated 8 studies utilizing 2 approaches: the exhaustive and incumbent Line-Item Tool, and the new Sizing Tool. Table 1 shows effort estimates were, on average, within ~2% of each other – confirming the accuracy of the new tool. Table 2 shows that staff required ~90% less time to create estimates using the new Sizing Tool (an aggregate savings of 27 hours over 8 studies) – demonstrating significant reduction in administrative burden.

TABLE 1:
Calculated CRC Effort Estimate (hours)

Trial #	Line-Item Tool	New Sizing Tool	Delta
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	3361	+20.3%
Average	**32,809**	**33,513**	**+2.1%**

TABLE 2:
Estimate Creation Time (hours)

Trial #	Line-Item Tool	New Sizing Tool	Delta
1	4	0.50	-87.5%
2	6	0.75	-87.5%
3	2	0.15	-92.5%
4	5	0.50	-90.0%
5	3	0.25	-91.7%
6	3	0.25	-91.7%
7	4	0.25	-93.8%
8	3	0.25	-91.7%
Total	**30**	**2.90**	**-90.3%**

*This trial's PI asserted the new Sizing Tool better reflected the actual CRC support required.

DISCUSSION

The third project phase of developing the Management Tool to align staffing to workload is currently under way. The goal is to surface insights about staffing assignments and team capacity, to enable supervisors and managers to effectively align staffing to workload.

Concurrently, the team is exploring opportunities to improve the Sizing Tool and Tracking Tool. Examples include:

- Refine workload estimates to better reflect post COVID-19 workflows.
- Expand the IT infrastructure to support backups and concurrent usage.

CONCLUSIONS

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