Conquering Resourcing

BJ Broome[1], Dinesh Pal Mudaranthakam[1]

1. **The University of Kansas Cancer Center, Kansas City, KS, USA,**

Introduction

The University of Kansas Cancer Center (KUCC) Clinical Trials Office supports varying oncology clinical trials. Each trial is unique in design, complexity, accrual goals and deliverables with participants in varying stages participation. Ensuring appropriate resourcing across clinical research coordinators and clinical data coordinators is an every evolving challenge. Under or over utilization and resources leads to missteps in trial execution, data quality and timeliness, decline in morale, turnover and decreased participant satisfaction. To combat these challenges, The KUCC Clinical Trials Office has capitalized on existing resourcing tools and developed a robust resourcing algorithm.

GOALS

Develop an objective resourcing algorithm utilizing a clinical trials management system to allow:

- Assessment and alignment of workload
- Evaluation of staff performance
- Justification of staffing needs
- Appropriate budgeting for effort (pharma, grant, internal)
- Trial prioritization
- Transparency

Methods

Utilizing the Ontario Protocol Assessment Level[2] (OPAL) too as a guide to developing a protocol complexity score with a ranking scale of 1 (non-treatment/simplistic) through 8 (Phase I/CAR-T/highly complex), we modified the criteria to expand upon scoring criteria using “add-on” protocol requirements that can increase the complexity (i.e. requirement of multiple portal use).

From there we surveyed clinical research leaders, coordinators, and data managers with varying experience levels regarding overall amount of effort, measured by hours of work and visit type for each level of trial complexity. Thus turning objective data into subjective data. (Table 1).

Once hours of work were established, we incorporated all components of the calculation in to our clinical trials management system allowing for the automated calculation of hours of work for individual clinical and data coordinators.

Table 1

Visit Hours Based on Protocol Complexity and are calculated on a per visit basis (see additional sheet for justifications):									
Score (Based on Protocol Complexity and any add ons)	CRC Hrs Screen	CRC Hrs Actively On Tx	CRC Hrs F/U	CRC Hrs Survival Only		Data Hrs Screen	Data Hrs Actively On Tx	Data Hrs F/U	Data Hrs Survival Only
1	1	0.5	0	0		0.5	0.25	0	0
2	1	0.5	0	0		0.5	0.25	0	0
3	1	1	0.5	0.25		0.5	0.5	0.25	0.25
4	2.5	1	0.5	0.25		1	0.5	0.25	0.25
5	4	1.5	1	0.25		2	1	0.5	0.25
6	6	2	1	0.25		2	1	0.5	0.25
7	8	3	1.5	0.25		6	1.5	1	0.25
8	8	4	2	0.25		8	2	1	0.25
>8	10	5	3	0.25		9	3	1.5	0.25

[2]Smuck, B., Bettello, P., Berghout, K., Hanna, T., Kowaleski, B., Phippard, L., . . . Friel, K. (2011). Ontario Protocol Assessment Level: Clinical Trial Complexity Rating Tool for Workload Planning in Oncology Clinical Trials. *Journal of Oncology Practice, 7*(2), 80-84. doi:10.1200/jop.2010.000051

Results

In calendar year 2019, total number of study hours for Clinical Research Coordinators was 88,942 and clinical data coordinators 50,013. Considering the annual hours worked as 2080, this results in the need for 43 clinical research coordinators and 24 clinical data coordinators.

The algorithm’s calculations for resources needed almost mirrored the resources available (assuming all positions filled). This implies the need for better workload distribution among staff as there are areas in which acuity is higher and staff members are working increased hours.

Additional vetting is needed to solidify the algorithm as well as considerations for community site staff, program alignment and expected growth.

Future Directions

Once finalized, this resourcing report will be used to provide oversight of resources as a whole, ensure adequate budgeting for clinical trial effort, consideration in disease specific working groups on trial selection and justification for additional resources.