Category: Clinical Trials Operations - Work in Progress

Conquering Resourcing

B. Broome, D. Pal Mudaranthakam

The University of Kansas Cancer Center

1. Background

Resourcing for clinical trials is a complex process, and achieving a balanced workload is a difficult task. Advocating for resources and ensuring all staff is working at capacity is a delicate balance that all clinical trial offices struggle to maintain. This is particularly difficult for clinical research coordinators and clinical data coordinator workloads. To balance workloads and ensure appropriate resourcing, leaders must consider trial types, complexity, ancillary department coordination, and visit types. With this as a goal, a workload algorithm was created to measure clinical and data coordinator resources objectively.

2. Goals

To evaluate current staffing capacity and needs, the KUCC workload algorithm was created to assess:

1. the current volume of work for individual clinical research coordinator and clinical data coordinator,
2. for realignment of resources to balance workloads across staff, and
3. quantify resourcing needs

3. Solutions and Methods

Modifying the OPAL assessment to utilize subjective data to create objective data for supporting resources. Collaborating with our clinical trial management system administrator to build a resourcing algorithm looking at actual hours of work based on trial type.

Example:

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	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

4. Outcomes

Utilizing the methods implemented reviewing historical data specifically within the Early Phase program proved the resourcing algorithm to be on target for determining resourcing needs. With this confirmation, we moved forward with implementation across all trial.

5. Lessons Learned

Some of the lessons learned were, modifications to the algorithm were needed to capture work. We identified areas where we were not capturing the information needed to develop the algorithm. Tools to capture appropriate information was needed before testing the algorithm.

Future directions will be to utilize this reporting for ensuring staff is working at capacity, standardizing expectations, and realigning staff as needed. This resourcing tool will be used to justify additional staffing needs objectively, and support budgeting for trials. Eventually, we would like to incorporate the expected workload burden of a trial during disease working group review as a point for consideration when voting on trials.