Conquering Resourcing
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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 of participation. Ensuring appropriate resourcing across clinical research coordinators and clinical data coordinators is an 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.

Methods
Utilizing the Ontario Protocol Assessment Level² (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 into our clinical trials management system allowing for the automated calculation of hours of work for individual clinical and data coordinators.

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.

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

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.

Table 1

\begin{table}[h]
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\begin{tabular}{|c|c|c|c|c|c|c|c|}
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Score Based on Protocol Complexity and are calculated as a part of trial design (please add additional data for full calculation):
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CRC hrs Screen & CRC hrs Activity On or Off & CRC hrs FU & CRC hrs Survival Only & Data hrs Screen & Data hrs Activity On or Off & Data hrs FU & Data hrs Survival Only \\
\hline
1 & 0.15 & 0.25 & 0.15 & 0.25 & 0.15 & 0.25 & 0.15 \\
2 & 0.30 & 0.50 & 0.30 & 0.50 & 0.30 & 0.50 & 0.30 \\
3 & 0.45 & 0.75 & 0.45 & 0.75 & 0.45 & 0.75 & 0.45 \\
4 & 0.60 & 1.00 & 0.60 & 1.00 & 0.60 & 1.00 & 0.60 \\
5 & 0.75 & 1.25 & 0.75 & 1.25 & 0.75 & 1.25 & 0.75 \\
6 & 0.90 & 1.50 & 0.90 & 1.50 & 0.90 & 1.50 & 0.90 \\
7 & 1.05 & 1.75 & 1.05 & 1.75 & 1.05 & 1.75 & 1.05 \\
8 & 1.20 & 2.00 & 1.20 & 2.00 & 1.20 & 2.00 & 1.20 \\
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