Category: Investigator-Initiated Trials – Completed Project

Development of a Workload Assessment Tool for Investigator-Initiated Trial Protocol Development Based on the Ontario Protocol Assessment Level Scale

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1. Background
Workload assessment tools provide valuable objective insights into personnel management and workforce planning, which is especially needed for new or rapidly growing teams. Existing workload assessment tools in clinical research, such as the Ontario Protocol Assessment Level (OPAL) scoring tool, are generally intended for application to the role of the clinical research coordinator. Due to a growing portfolio of investigator-initiated trials (IITs) at Cedars-Sinai (CS) Cancer, an objective measure of workload for IIT protocol development specialists was needed to inform equitable new trial assignments and to justify the addition of personnel.

2. Goals
To develop a tool to provide an objective assessment of workload per full-time equivalent (FTE) for IIT protocol development specialists, to provide a basis for tracking ongoing metrics, to inform new trial assignments to protocol development staff members, and to generate baseline data to demonstrate growth over time and to justify the addition of FTEs.

3. Solutions and Methods
Due to its familiarity in the clinical research field, the OPAL tool was selected for modification for application to IIT protocol development staff at CS Cancer. The scope of studies supported by the protocol development team were ranked from 1-8, in order of increasing complexity. Factors contributing to increasing IIT complexity included classification as treatment vs. non-treatment; scope of multi- vs. single-site; Phase I vs. non-Phase I; and trials with an investigator-held IND vs. IND-exempt studies. For single-site studies only, once the trial has opened to accrual, a multiplier of 0.5 was applied. Closed-to-accrual studies did not contribute to the workload assessment. Each trial in the portfolio was categorized according to the tool and assigned a numeric score. A summary score and an average complexity score was generated for each FTE, to provide a snapshot of both the total workload and the average complexity of their portfolio. Per FTE, the average number of studies contributing to the score was 11 (range 9-14); the average summary score was 33 (range 28.5-37.5); and the average complexity score was 3.1 (range 2.7-3.7).

4. Outcomes
These data points, taken into consideration along with the individual's level of experience, administrative responsibilities, existing relationships with investigators and study teams, and career interests and goals, are used to inform equitable future trial assignments, which may contribute to improved staff morale and retention. In addition, when the scope of the protocol development team grew to take on an additional study team portfolio, the newly added trials were scored, which provided objective rationale for increasing the size of the team, and an additional staff member was hired.

5. Lessons Learned and Future Directions
This tool provides objective assessments of workload that resonate with cancer center leadership. In addition, it provides staff members with assurance that new trial assignments are made with objective consideration of existing workload and in the spirit of equity. While the tool reflects the range of trials

supported by protocol development staff at CS Cancer, this tool can readily be modified to reflect the scope of other centers. The tool would benefit from additional validation of the categorization as well as correlation of scores to FTEs.

Figure: