

## **Assessing Clinical Trial Complexity and Clinical Research Study Team Capacity by Sylvester Workload Assessment Tool (S.W.A.T.)**

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### **1. Background**

Measuring workload activities of clinical research coordinators (CRC) and clinical research data specialists poses a challenge for clinical managers. The University of Miami, Sylvester Comprehensive Cancer Center employs 100+ CRCs to support 500+ active clinical trials including Investigator-Initiated Trials (IITs). Without dependable, widespread, published data for workload measurement in clinical research, management has initiated clinical trials without appropriate consideration of the associated workload, complexity of the trials, and capacity of the study team. The result of such application is impractical performance expectations, overburdened study team leading to reduced retention rates, inefficient utilization of resources, and a risk to patient safety and/or data integrity. Therefore, it is vital to improve understanding of the protocol, time commitment of different assessments, and resources required for a department to participate in a clinical trial.

### **2. Goals**

The team aimed to establish a standardized model to evaluate protocol complexity and study team capacity for staffing and workload management throughout the departments. This would be accomplished by:

- Creating a rating scale to rank protocols on complexity by scoring various trial elements.
- Assign trials a score at the Feasibility Review Committee.
- Assess staffing workload on a per protocol basis throughout all departments (e.g., site disease group, regulatory support, clinical research nursing).
- Track study team assignments through a workload tracker.
- Evaluate study team workload by Human Resources and/or an independent consulting team.

### **3. Solutions and Methods**

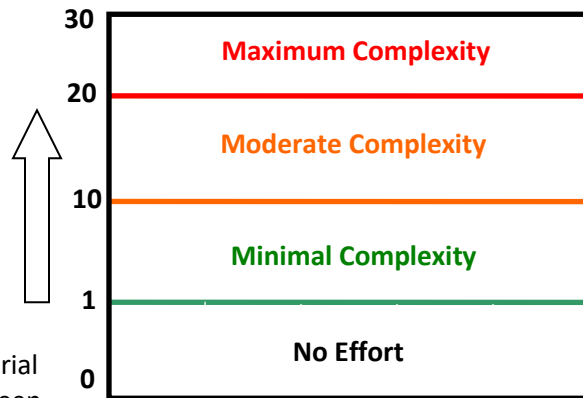
*“Creating a rating scale.”*

To gauge the required effort from the study team for a specific clinical trial, a workload assessment instrument was devised. The objectives of such instrument were to (1) develop a standardized rating scale to evaluate clinical trial complexity, and (2) reference the score when assigning clinical trials and/or patients to study team members. A set of guiding principles was formulated to serve as the framework for this project. According to these principles, the instrument must (1) be simple to apply, (2) measure study-specific assessments for clinical research staff in all departments, (3) aid in determining workload capacity, and (4) include industry trials, cooperative group trials, and IITs. Ultimately, the Sylvester Workload Assessment Tool (S.W.A.T.) was developed. The tool was based on the NCI Trial Complexity and Elements Scoring Model, which was one of the earliest models to quantify clinical trial associated workloads.

Based on ten elements of a protocol, the S.W.A.T. would grade the complexity of a trial and provide a numerical score. The ten elements are:

1. Stratification (# of study arms)
2. Registration/Screening Process

3. Complexity of Investigational Therapy
4. Length of Treatment Regimen/s
5. Specimen Collection
6. # of Disciplines/Departments Involved
7. Data Collection Complexity
8. Ancillary Tiers
9. Follow-Up Requisites
10. Monitoring/Audit Visits



Each element is divided into three sub-levels which can be scored 0, 1, 2, or 3. A score of 0 indicates the trial requires no effort from the study team. A score between 1 – 10 indicates minimal effort and would be suited for a CRC 1. A score between 11 – 20 indicates a moderate effort and would be suited for a CRC 2. Lastly, a score  $\geq 21$  indicates maximum effort and would be suited for a CRC 3.

*“Assess staffing workload.”*

A workload tracker was devised by the clinical manager. Both the clinical manager and study team member documented the patients the individual was assigned to or the visits they supported for each trial (in the case of collaborative effort). The University of Miami’s Human Resource department and Huron consulting firm denoted patient workload per CRC in an independent review. When combined with the effort value from the S.W.A.T., monthly efforts, in terms of per-patient, were assessed each month.

**4. Outcomes**

The S.W.A.T. facilitated a more nuanced understanding of the workload associated with each clinical trial. This insight allowed for a more equitable distribution of tasks among research staff, ensuring that each team member was appropriately matched to trials that aligned with their skillsets. Understanding the complexity of trials enables targeted staff training and support initiatives. Staff members are equipped with the necessary skills and knowledge to handle trials effectively, improving overall trial outcomes.

The staffing workload assessment proved to be an invaluable tool in understanding the dynamics of our team's workload distribution. By meticulously evaluating each staff member's capacity and the complexity of their assigned tasks, we gained a holistic perspective on the functioning of our workforce. One of the notable outcomes was the establishment of clear benchmarks for workload expectations. This has not only provided transparency in assessing individual contributions but has also allowed us to set realistic performance standards for our team members. It provides a standardized framework to evaluate individual contributions, fostering a culture of accountability and recognition within the team.

The assessment outcomes have proven instrumental in justifying our current staffing levels. The insights derived from the assessment have played a crucial role in our budget planning endeavors. The data-driven approach allows us to allocate resources more effectively, ensuring that we can meet the demands of our projects without overburdening our staff. In addition, we were able to provide compensation adjustments for three meritorious staff and identify an additional three staff for promotions all in a department. This process contributed to the team’s productivity and morale.

## **5. Lessons Learned and Future Directions**

The S.W.A.T. score provided insights into the required level of CRC support for the clinical trial. For instance, a score of 27 signified a high-complexity trial, leading to assignment to a CRC3. By redistributing complex trials away from CRC1 and CRC2, these team members could focus on trials aligning with their skillsets. When considering a CRC for promotion, we assigned a patient from the next level to assess their readiness, ensuring promotions were not premature.

Routine evaluations are essential to gauge each staff member's workload related to clinical trials and assess their capacity to handle the complexity of their tasks. The acquired data aids research programs in setting benchmarks, tracking trends, justifying current staffing levels, identifying the necessity for additional staff, aiding in budget planning, establishing metrics for staff performance, ensuring workload equilibrium, and ultimately enhancing staff satisfaction. This comprehensive approach may contribute to reducing staff burnout and turnover.