

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

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Background

Assessing the workload of clinical research coordinators (CRC) and clinical research data specialists (CRDS) presented a challenge for clinical managers. At the University of Miami, Sylvester Comprehensive Cancer Center, over 100 CRCs support 500+ active clinical trials, including Investigator-Initiated Trials (IITs). The absence of reliable, widely available workload measurement data in clinical research led management to launch trials without adequately considering workload, trial complexity, and team capacity. This resulted in unrealistic performance expectations, overburdened study teams, decreased retention rates, inefficient resource allocation, and risk to patient safety/data integrity. Thus, enhanced understanding of protocol requirements, assessment of time commitments, and resource needs for clinical trial participation was imperative.

Goals

The objective was to develop a standardized model for assessing protocol complexity and team capacity in order to effectively manage staffing and workload across departments. The endeavor entailed:

- Creating a rating scale to rank protocols on complexity by scoring various trial elements.
- Assigning trials a weighted numerical complexity score at the Feasibility Review Committee to forecast the project trial workload of current FTEs.
- Assessing staffing workload on a per protocol basis throughout all departments (e.g. site disease group, regulatory support, clinical research nursing).
- Utilizing a workload tracker to monitor study team assignments and assessing the current trial workload of FTEs on a monthly basis.
- Evaluating study team workload by Human Resources and/or an independent consulting team.

Methods

To achieve the stated objective, we subdivided the task into two components.

Create a Rating Scale

To assess the effort required from the study team for specific clinical trials, a workload assessment tool was created. Its objectives were to establish a standardized rating scale for evaluating trial complexity and to utilize this score in assigning trials and patients to team members. Guiding principles were formulated, emphasizing simplicity, measurement of study-specific assessments across departments, aiding workload capacity determination, and inclusion of various trial types. The outcome was the development of the Sylvester Workload Assessment Tool (S.W.A.T.).

The S.W.A.T. employed ten protocol elements to assign a weighted numerical score, tailored for the study designs and reporting standards prevalent at SCCC-CRS. These elements included: Stratification (number of study arms), Registration/Screening Process, Complexity of Investigational Therapy, Length of Treatment Regimen/s, Specimen Collection, Number of Disciplines/Departments Involved, Data Collection Complexity, Subsidiary Strata, Follow-Up Requisites, and Monitoring/Audit Visits.

Assess Staffing Workload

A comprehensive departmental workload tracker was established, enabling clinical managers to document patient assignments or supported visits for each trial (e.g. collaborative efforts between SDGs). The Huron consulting firm conducted an independent evaluation of patient workload per CRC. This data, coupled with S.W.A.T. effort values, facilitated monthly assessments of effort per patient.

Outcome

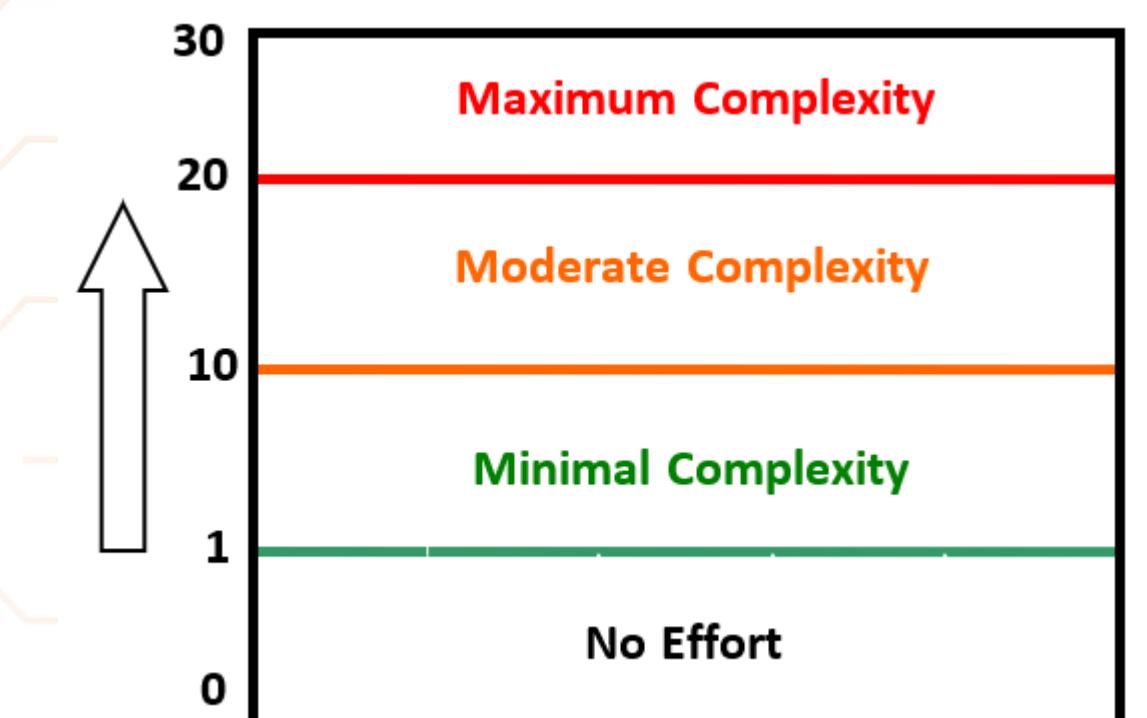
The scoring of elements initially assigned equal weight to all items, yet certain factors exerted a more significant influence on study complexity. For instance, the extent of data collection and requirements for reporting serious adverse events had a greater impact on coordinator effort compared to internal billing requirements or the duration of a study subject's visit. Consequently, a review of the 21 elements was conducted, and those deemed to significantly impact complexity were assigned weighted scores.

Scores were weighted using multipliers ranging from 1.0 to 2.0 across all 10 items. Less complex or time-intensive items were assigned a multiplier of 1.0 (e.g., follow-up requisites), while the most complex and time-consuming items were assigned a multiplier of 2.0 (e.g., multiple-step screening phases with combined modalities).

SCCC-CRS evaluated the S.W.A.T. scores during the initial trial feasibility phase, conducted at the Feasibility Review Committee (FRC) meeting. Subsequently, these findings were presented at the SDG meeting, where trials exhibiting underperformance could be earmarked for closure to alleviate workload burdens. Principal Investigators were advised that in instances of limited staff capacity, clinical research leadership would offer guidance and support to help investigators in declining sponsor and CRO requests to initiate low-priority trials.

In addition, The S.W.A.T. served as a predictive measure of how much coordinator effort should be budgeted for a clinical trial. The assessment outcomes justified our current staffing levels and informed budget planning efforts. Data-driven resource allocation ensured project demands are met without overburdening staff. Additionally, multiple deserving staff received compensation adjustments or identified for promotions within the department, contributing to team productivity and morale.

The S.W.A.T. facilitated a comprehensive understanding of the workload associated with each clinical trial, enabling an equitable distribution of tasks among research staff based on their skillsets. This insight supported targeted training initiatives, equipping staff with the necessary skills to handle trials effectively, thus enhancing overall trial outcomes.



Each element comprises three sub-levels, scored from 0 to 3. A score of 0 denotes minimal effort required from the study team. Scores ranging from 1 to 10 indicate minimal effort, suitable for a CRC 1. Multipliers (1.0 – 2.0) were assigned to each element of the tool. Scores between 11 and 20 suggest moderate effort, suitable for a CRC 2. Scores exceeding 21 signify maximum effort, appropriate for a CRC 3.

Future Plans

In this initial version of the S.W.A.T., we opted to focus solely on CRC activities specific to study trials, employing a limited range of weights for simplicity. Based on the current activities factored into the S.W.A.T. score calculation, it's estimated to encompass approximately 80% of CRC activities (data not disclosed). The remaining 20% of time is allocated to additional tasks like Good Clinical Practice and IATA training, PI Oversight Meetings, scheduling, and further training, which vary in weight and may differ for junior and senior CRCs depending on their roles at SCCC-CRS. To optimize staff productivity, it is essential to allocate protected time for staff to fulfill research-related duties and acquire certifications pertinent to clinical trials. We intend to incorporate a more comprehensive list of activities into the S.W.A.T. algorithm in future iterations.

Our analysis of the mean S.W.A.T. score for experienced CRCs suggests that a 20% increase in that score would indicate excessive workload, potentially jeopardizing the quality of work, a critical aspect of clinical research. This finding warrants independent validation in diverse organizational contexts. Additionally, we propose that the S.W.A.T. could serve as a tool for prospectively assessing the complexity and feasibility of new clinical trials.