

A task-based automated comprehensive assessment tool for clinical trial-associated workload

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1. Background

The accurate and efficient assessment of workload enables the effective deployment of research personnel to support clinical trials. Workload assessment enables managers to distribute workload among the research staff more evenly, which prevents staff burnout and reduces turnover. However, this evaluation is intricate by the development of increasingly complex trials, more restrictive patient criteria, decreased funding, and subjective trial assessments. We have developed an objective, task-based acuity assessment tool that utilizes real-time data produced by our internally developed Clinical Trails Management Application (CTMA) to measure workload.

2. Goals

Our complexity assessment tool evaluates the time spent on various tasks performed over the course of the clinical trial life cycle including study start up, diagnostic testing requirements, scheduling, treatment day visits, safety, modifications, data gathering and entry, queries, monitoring/audit, and other administrative tasks. Using this information, we have analyzed the acuity of each employee (Research Nurses, Data Coordinators, Safety Specialists, and Regulatory Specialists), which has enabled our managers to make objective decisions on staffing and workload distribution while also monitoring compliance and efficacy. We have set 2,000 work hours ($\pm 5\%$) per year as the benchmark goal per full-time equivalent (FTE) and adjusted the study and patient assignment based on the real-time assessment of this benchmark.

3. Solutions and Methods

CTMA documents information related to all aspects of the clinical trial life cycle, including study start up, patient enrollment, study visits, queries and other administrative tasks. This information is linked to each staff member to accurately measure his/her workload. Real-time data is analyzed by a pre-designed algorithm that will automatically calculate time spent per task category. The algorithm for each job category (Nursing, Data, Regulatory, Safety) was developed by employee working groups. The data is analyzed and made available to management, and can be drilled down to the staff, disease center, and department level.

4. Outcomes and Future Directions

The outcome will allow us to accurately assess cumulative workload, completed vs anticipated workload per employee based on existing studies and patient load. In addition, it will provide real-time compliance information that will improve corrective action effectiveness. Using this data, we have reassigned active patients evenly among the Research Nurses, and shuffled FTEs between disease centers based on complexity rather than number of open trials and accruals, which do not necessarily translate to increased workload. The data will also allow for a projection of time to any point throughout the year (quarterly, biannually, annually) so that the workload can be distributed appropriately by

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management. In addition, the information will enable management to make more informed decisions about overall staffing and budgeting of trials and provides a foundation for higher level financial and efficiency analyses.

The complexity assessment can be used to assess a variety of activities based on the information compiled. Our center is conducting a comprehensive analysis of a variety of critical areas in clinical research including time to activation, cost outs, invoicing, query analysis, and regulatory tracking. Most importantly, transparent assessment of workload has resulted in increased employee satisfaction based on internal HR surveys.