

The Need for a Standards-Based Approach to Staff Workload Tracking: A Case Study

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Staff effort-tracking, otherwise referred to as staff workload assessment, in clinical trials is commonly defined as the process of objectively quantifying the time it takes for staff to complete study tasks in order to determine the costs of conducting clinical trials and support equitable workloads among staff. It employs a data-driven approach, whereby staff record the time they spend on trial activities. It is a topic that has become increasingly popular, as sites look to gain greater control over operations and support more balanced workloads.¹⁻³

This article addresses the benefits and challenges that sites face when implementing staff effort-tracking processes. It also examines a case study of organizations that collaborated to establish goals and define processes and tools, demonstrating the need for a standards-based approach to effort-tracking.

Staff Effort-Tracking Overview: BENEFITS

Sites have identified two main motivations for tracking staff effort in clinical trials:

- More accurate trial budgeting and negotiation with sponsors
- Proper workload planning for staff to ensure efficient and effective outcomes of clinical trials

Many site budgets are too low to provide adequate compensation for the work completed. Sites do not have proper insight into the time required for certain trial activities and, therefore, do not have insight into the associated costs of those activities. Furthermore, negotiations with sponsors can be difficult without documentation to justify the time it takes for staff to complete trial activities.³

Workload planning is another value of tracking staff effort. Organizations can more easily grasp how many staff members are needed to ensure effective and compliant outcomes for trials. This can help sites more accurately estimate the number of trials they can conduct at a given time.³

Without staff effort-tracking, an organization may struggle with determining capacity and scope for an individual employee. This can lead to staff members who are overloaded or underemployed in their roles. Furthermore, workload planning can be an important element in efforts to maintain staff morale.

When the Indiana University Simon Cancer Center conducted a staff survey, one of the largest frustrations among staff was an unbalanced workload. Also, the center has looked to effort-tracking as an opportunity to identify where a staff member may need more training in his or her role.⁴

Tracking staff effort can also have a positive effect on staff hiring. It can provide the data needed to justify more staff if current staff members are overwhelmed in their workload, or are dedicating too much time to tasks that are outside the scope of their roles.⁵

The value of proper workload planning and hiring can be especially valuable in the current climate of increasing trial complexity. Respondents to a recent CenterWatch survey conducted among 269 coordinators reported that the typical trial has become more demanding.⁶

Staff Effort-Tracking Overview: CHALLENGES

Although there is clear value behind tracking staff effort, the process has yet to become widely adopted across sites,³ largely due to a lack of foundational elements that must be put in place before site staff can be confident in the process of collecting and analyzing data. The following are common challenges that sites face in tracking staff effort:



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Determining the Types of Data Needed

Knowing where to begin in terms of data collection can be difficult, because many organizations may not know the questions they are trying to answer and, therefore, don't know what data to collect. Are they trying to define where the most time is spent so they can evaluate potential process changes to make roles more efficient, or to justify adding staff members? Or do they want to redefine job descriptions and split the workloads across multiple groups?

Further, how detailed should the tasks be to provide quality data from which an institution can glean valuable information and put solutions into action? Should the data be an overview of high-level tasks performed or provide more detail (e.g., patient education versus patient education about lab results, patient education about treatment options, etc.)?

Although it may appear advantageous to seek detailed data, if tasks are too detailed, it could become difficult for staff members to record data accurately and consistently. Organizations must find a balance when determining the types of data to collect.

Dedicating Staff Time

Although preferred methodology has been identified, such as time-and-motion studies,³ such methods have been considered by many to be too time consuming, as they require staff to manually document their efforts.³ If the level of detail required to be recorded is too high, it can also be time consuming for staff members to record it. The potential consequences are that staff could enter data inconsistently (or not at all), and the resulting measurements may not be as accurate as desired.

Gaining Staff Participation

Obtaining staff participation can also be challenging for various reasons. The work of effort-tracking may seem demeaning or be too time consuming.⁸

Another challenge can be the staff perception that they are being micromanaged, or that the data will be used to reprimand them. For example, if most nurses take 30 minutes to complete a task, but one staff member consistently takes 60 or more minutes to complete the same task, would that staff member be seen as being inefficient? This is a real concern among staff.

Such negative perceptions can ultimately hamper staff participation, and participation is key to collecting useful data and taking action.

Maintaining Data Quality and Consistency

Another challenge involves properly categorizing tasks so they are clear and consistent across an organization. This requires understanding the tasks performed across studies, and clearly communicating definitions to staff to ensure that data are recorded properly. Also, the system in which staff members record their time must be easy to understand and use. Without consistent data, an organization is unable to rely on the results to provide accurate analyses.

Overcoming Challenges Through Established Standards: A Case Study

Given the clear benefits, yet significant challenges, in implementing effort-tracking practices, a standards-based approach can assist organizations in quickly adopting processes that result in quality data and actionable analyses. Furthermore, establishing common datasets enables organizations to accurately compare their data to peer organizations and identify inefficiencies in operations.

Recognizing the benefits, organizations have begun to establish standards-based approaches to staff effort-tracking. In the United Kingdom, for example, the European Organization for Research and Treatment of Cancer worked collaboratively with cancer centers to identify a standard set of tasks and subtasks for tracking effort among staff. A tool was developed with the common dataset and piloted across numerous organizations. The work has culminated in standard tools available for use across sites.²

Similarly, a group of research organizations in the United States collaborated under the umbrella title of Onsemble³ to devise an approach that could overcome the challenges associated with staff effort-tracking. The group consisted of seven academic research organizations that employ a common clinical trial management system.

The remainder of this article focuses on the work done by the Onsemble group to create a standard effort-tracking approach. It also illustrates how the approach was implemented, and the resulting effects on operations at one participating institution.

Determining What Needs to Be Collected and Creating a Common Dataset

The Onsemble group first addressed the idea of creating standards by focusing on establishing a common dataset. To do so, the group members asked questions they wanted answers to at their institution, such as "How much time does it take to open a new trial?" and "How much time does it take to open a trial to accrual?"

The dataset gathered details that extended from study startup throughout the lifecycle of the trial to closeout. From there, the organizations set out to identify how much time is spent on specific tasks and who performs them. Furthermore, the group measured other variables related to the study, including sponsor type, phase, and whether or not it was managed by a contract research organization.

Once the goals of the collaboration were set, the organizations worked to define stages of a trial that were important to track. These included:

- Startup
- Active
- Follow-up
- Closeout

Categories were then defined and put into the following buckets:

- Budgeting
- Contracting
- Data management
- Regulatory
- Clinical activity/coordination

The group then also defined tasks within each category, such as amendments, patient care, vendor inquiries, serious adverse event management, and contract negotiation.

Saving Staff Time and Maintaining Consistency with a Standards-Based Tool

To implement effort-tracking processes that would not impede research staff in their day-to-day activities, a standard effort-tracking tool was developed based on the defined stages, categories, and tasks.

With the tool, staff were able to log into a system that allowed them to enter data according to the stage and category of trial activity, guiding them in their data entry and helping to ensure consistent data among staff.

Indiana University Simon Cancer Center, an Onsemble collaboration participant, also created a corresponding user guide¹² to ensure that staff were knowledgeable about the types of information being recorded and the corresponding definitions.

Obtaining Staff Participation

Indiana University Simon Cancer Center initiated a six-month pilot project to track industry-sponsored studies. The center began by recruiting volunteers from different operational areas.

When requesting volunteers, the center said that the pilot project was an opportunity for staff to demonstrate challenges in their workloads. Staff members saw it as a chance to justify frustrations with their workload and show how much time was spent on certain activities. Volunteers included a research nurse, a finance representative, a regulatory representative, and a study coordinator. Each participant tracked his or her study activity for six months.

Following the pilot, university leadership mandated the use of effort-tracking at the organization. To promote continued engagement, the center

FIGURE 1. Nursing Effort in Hours on Active Industry Trials

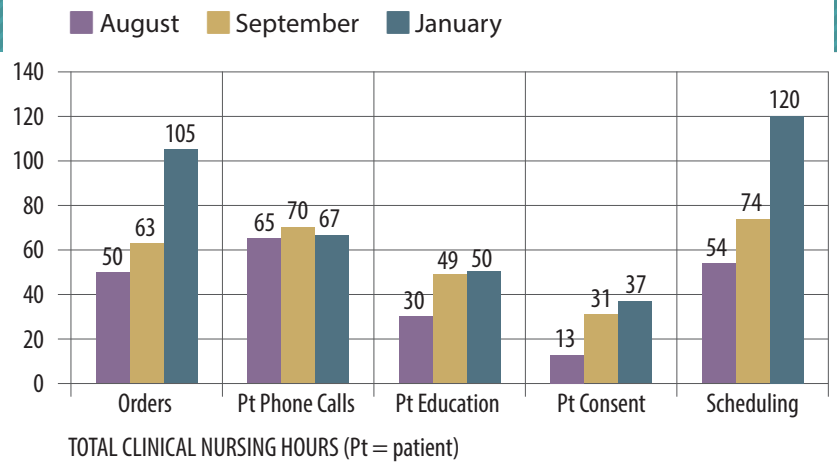
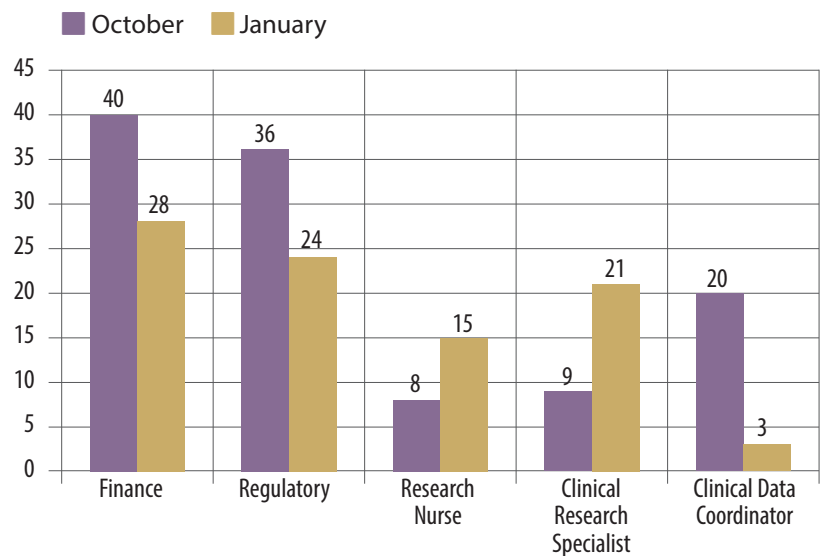


FIGURE 2. Startup: Average Hours per Full-Time Employee per Role



has shown the recorded data to staff in the form of reports to demonstrate that their efforts are being taken into account.

In addition, the Holden Comprehensive Cancer Center, part of the University of Iowa Hospitals and Clinics, recently implemented the standard effort-tracking tool that was developed with guidance from the Onsemble collaborative group. The center took a similar approach to that of Indiana, and recruited volunteers by communicating it as an opportunity to help coordinators get a handle on their workloads. The center received six volunteers from regulatory and clinical research associate areas.

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spent on certain activities, and recognition of the minimal amount of time it took to record activities. The Holden Comprehensive Cancer Center plans to include required effort-tracking as part of its team's daily performance goals in 2014.¹⁰

Assessing the Overall Effect on Operations

The Indiana University Simon Cancer Center recorded a multitude of data that gave unique insight into roles and activities over its six-month pilot project.⁵ This article discusses a couple of examples of actionable data that the center recorded.

As one example, the results of the data showed that research nurses were spending too much time on administrative tasks (see Figure 1). Recognizing the need for these nurses to refocus their efforts on patient care, the center used the statistics to justify hiring an additional full-time employee.

In a second example, the data showed that significant time was spent on financial tasks to open a study, greater than that of regulatory efforts (see Figure 2). Knowing these statistics, the center has been able to justify higher budgeting for these tasks, and is able to provide documentation for startup costs with sponsors, supporting more streamlined negotiation processes.

Future Direction of Staff Effort-Tracking

The standards-based approach employed by the collaboration presents an opportunity for organizations to learn more by comparing their measurements with other organizations, and to identify opportunities for greater efficiencies in workloads. As a direct result of this work, a platform has been created that offers all academic organizations a free standardized tool for tracking and analyzing staff effort. The tool also offers users at the organizations the ability to compare their anonymized data.¹¹

Conclusion

Given the benefits, yet significant challenges, of staff effort-tracking, sites clearly need defined processes and tools to effectively adopt the practice. As demonstrated by the work of the Onsemble collaboration and the results at Indiana University Simon Cancer Center, a standards-based approach assists sites with establishing clear goals, recording actionable data, and realizing significant benefit.

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