JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 2, No. 9, September 2006 "Can You Handle the Truth?"

Where Does the Time Go?

By Norman M. Goldfarb

Clinical research budgets for U.S. investigative sites are shrinking. At some point, budgets will stabilize, but the trend is unlikely to reverse because globalization of clinical research gives sponsors lower-cost options in developing countries. From 2002 to 2004, the U.S. share of 1572 filings dropped from 76% to 62%.[1] Site profitability therefore requires careful study selection, effective budget negotiations, and efficient cost management. All of these tasks require that sites understand their costs.

Investigative sites are labor-intensive, so most costs involve personnel time. Unfortunately, many study activities are hidden and do not show up in the budget. Figure 1 presents a short list of hidden costs. The Directory of Clinical Research Terminology (CRT) Codes presents a long list of hidden costs at http://www.firstclinical.com/resources/codes/

What Can Be Done?

Without cost information, it is difficult for sites to select profitable studies or make the case for higher budgets. Complaining about low budgets is not an effective negotiating strategy, especially when many sites sign the clinical trial agreement without any negotiation at all. Those sites may not enroll any subjects, but that's a problem for later.

Figure 1: Hidden Cost Examples

- Preparing source document forms
- Obtaining clarifications of the protocol
- Telephone prescreening
- Communicating with referral sources
- Preparing and faxing enrollment logs
- Receiving and managing clinical supplies
- Processing stipend checks
- Rescheduling subject visits
- Processing IND safety reports
- Retaining subjects
- Responding to data queries
- Completing the closeout report

Extracting more money from sponsors is not, however, the only possible course of action. Once sites have identified the most time-consuming activities, they can work to improve the efficiency of their operations, and possibly eliminate some unnecessary activities entirely. For example, master clinical trial agreements almost completely eliminate the contract negotiation process.[2] There are probably hundreds of ways the typical site can improve its productivity.

Useful time estimations require accurate data. The most accurate data requires detailed timekeeping. Long-term, detailed timekeeping is not practical, nor is it necessary. A week of data every three months is probably adequate to estimate costs and identify the best opportunities to improve efficiency.[3]

Merely studying productivity improves it. A workforce efficiency study in 1927-1932 at the Hawthorne Plant of the Western Electric Company in Cicero, Illinois demonstrated that what you watch improves – the "Hawthorne Effect". The author personally supervised a 25% productivity improvement during the initial baseline measurement phase of an efficiency program – with no management intervention – in the semiconductor industry. Higher productivity supports higher salaries, thereby reducing turnover, improving morale, and generally improving the quality and productivity of the workforce.

Investigators can sit down with their staffs to brainstorm ways to improve efficiency. An open and creative atmosphere is essential because once people have developed a routine, it can be very difficult for them to consider alternate approaches.

A suggestion programs is a powerful tool to drive incremental improvements. Incentives can put people in the mindset of looking for new ideas. The incentives do not have to be large. Group recognition and rewards can be very effective. For example, investigators can put five dollars into a fund for each suggestion. When the fund is large enough, everyone can enjoy an awards luncheon. The more suggestions, the more frequent the luncheons.

Training programs take time, but they pay off if they present ways to perform tasks efficiently and eliminate the time wasted remedying errors. Good standard operating procedures eliminate inefficient and redundant work.

In sites with multiple study coordinators, it is quite possible that each coordinator has a better way to do something than the others. Frederick Taylor, the father of industrial productivity, once studied workers shoveling coal. Shoveling coal is a relatively simple task, and one might expect relatively small variations, mostly due to the speed of shoveling. However, Taylor discovered wide variations in the productivity of workers doing the same task side-by-side under close supervision. It turned out that different workers had different techniques, and some techniques were much more efficient than others. For example, shovel loads varied from four to 30 pounds. Taylor determined that 21 pounds was the optimal load and designed new shovels accordingly. Once the workers were trained in using the new shovels, productivity increased dramatically. If productivity studies can be so effective for a simple task such as shoveling coal, there must be a role for them in our industry.

Some pharmaceutical companies benchmark their operations against competitors. Investigators can do the same. For example, how long should it take on average to complete a surveillance telephone call or process a stipend payment? The data from different sites are likely to show substantial differences. Lower numbers do not necessarily mean more efficient practices. They could mean that one sites does easier studies than another, or that a site takes unacceptable shortcuts. Effective benchmarking thus requires examination of the processes in more detail than just measuring total length of time. Benchmarking consultants can facilitate the process, and numerous, low-cost books are available to guide organizations through the process.

Eventually, sponsors may follow the lead of the automotive, retail and other industries in partnering with their suppliers – investigative sites – to improve productivity. Sponsors can work with their investigator partners to develop a competitive advantage over other sponsors that use different investigators.

It is not surprising that clinical research turns out to be a philanthropic activity for many investigators. Inexperienced sites can lose money on clinical research and not even know it. According to FDA data, only about 10% of investigators stay in the business for five years or more.[4] Those that survive and prosper make the effort to understand their costs and use the information to improve efficiency, select profitable studies, and negotiate effectively.

References

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