DATA MANAGEMENT AND TECHNOLOGY FORUM | Al O. Pacino II

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Trial Drift
The Revolution and the Evolution of Clinical Blended Learning™

A clinical blended learning approach minimizes trial drift and adds value to all parties involved in a clinical trials project, and thus minimizes the day-to-day challenges and issues associated with trial drift.

Stage 1: Looking Back

As we look back at the coined introduction of the "trial drift" phenomenon in an article first published in *The Monitor*'s Winter 2004 edition, we find this definition: "Trial drift occurs when the average interest level and knowledge base among clinical trial personnel deteriorate during the course of the trial. In other words, the longer the trial continues, the more it drifts, unless proper intervention occurs." (See Figure 1.)

Increasing awareness and understanding of this phenomenon have helped many organizations embrace the concept and begin looking for solutions to minimize issues related to the everyday management of clinical trials.

Stage 2: The Revolution

The introduction of electronic systems has always presented our industry with the opportunity to develop better ways to manage clinical trials. The initial paradigm as the technology revolution began was to develop technologies that gave the end users a final electronic solution that would force them to change. However, the introduction of new technologies has always come at the expense of painful learning curves for sponsors, contractors, and investigative sites. From the late 1990s to the early 2000s, tremendous transitional efforts by industry 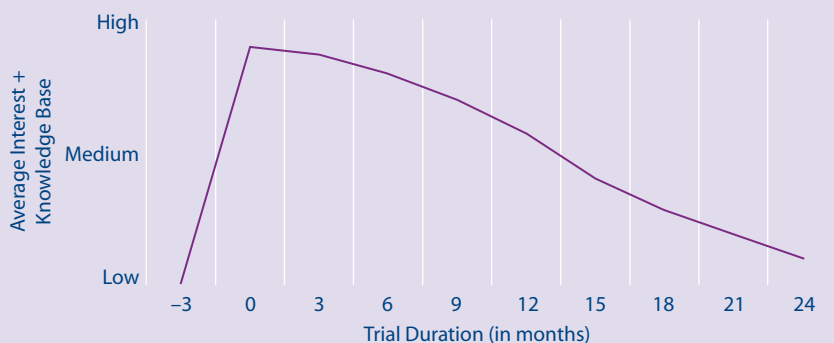leaders were confronted with strong resistance by the end users, and the speed of change eventually slowed almost to a halt.

As technology solutions improved their business models, more and more organizations began to embrace the concept of combating trial drift with suitable and more conservative technology solutions during their clinical trial planning stages. To quote again from the earlier *Monitor* article (and see Figure 2):

Obviously, proper trial planning is key to trial success. Planning can be improved by including experts with current and updated knowledge in a specific therapeutic area, up to date in training and communications technology and with current knowledge of productive investigative sites. This is especially important because a site deemed efficient several years ago may no longer be considered efficient given today's standards, mostly due to the inability or a laggard attitude for technology adaptation. Patients are becoming more educated and tend to migrate towards the best and latest therapies. Such experts often have better information on state-of-the-art technology designed to streamline clinical research processes and minimize trial drift—and choosing the proper platform is essential.

Over the years we have learned that an appropriate training and communications strategy is a must to the success of any clinical trial. As inefficiencies increase, training should be increased to head off knowledge drift. The inability to assess and benchmark

Figure 1. Trial Drift

Note: Low interest at (−3) months, increasing at investigator meeting (0). Drifting interest and knowledge base throughout the duration of the clinical trial.

knowledge drift in a clinical trial can profoundly affect trial management, and in some cases, can delay communications, thus the ability to address the problem quickly.

Stage 3: The Evolution of Clinical Blended Learning™

Painfully, the old paradigm for developing technologies that make end users change (referred to above) has evolved. Over the past few years, technology developments have increasingly been influenced by end users and investigative site staff members involved in clinical trials, and decreasingly influenced by IT and software developers.

Technology is molded to the need of the end user as the need arises, which has led to a slower, but more acceptable, transition to user-friendly technologies

within our industry, and thus to embracing the concept of Clinical Blended Learning™ for educational purposes. Clinical Blended Learning™ is a logical, simple, reasonable, and convenient compromise between the standard approach to education taken in project initiation meetings and the introduction of online technology solutions (see Figure 3).

Benefits to Interested Parties

As readers learned in the earlier *Monitor* article:

> Trial drift in one area of a study can produce a chain reaction that can be difficult to control. Poor inter-rater reliability in patient recruiting may result in poor recruiting skills, which in turn may limit patient pools and a

Figure 2. Trial Drift Intervention

Note: Low interest at (−3) months, increasing at investigator meeting (0). High interest and knowledge base maintained throughout the duration of the clinical trial.

clinical trial timeline drift. Planned study goals can change due to the shift in attention paid to clean ups and fire drills, which can make it difficult to collect and manage data properly. The inappropriate and inefficient use of technology vehicles for staff education and assessment, especially at the investigative site level, can lead to staff frustration and decreased interest in the study. Improper training and communications planning can damage the staff's knowledge base and enthusiasm, and erode managerial control.

Therefore we must identify the benefits of Clinical Blended Learning™ to all parties involved.
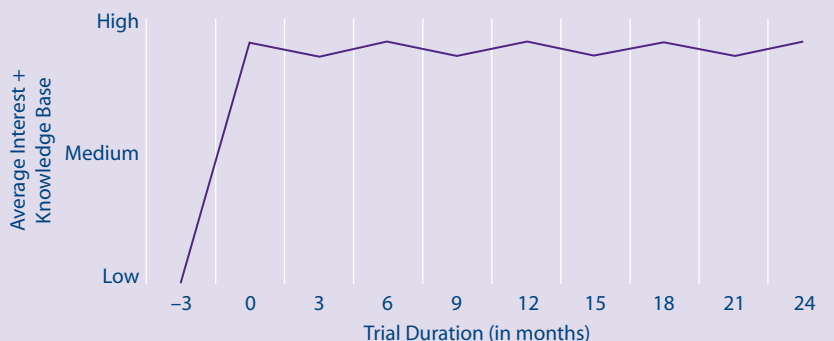
Regulatory Benefits

As regulatory agencies increase scrutiny before, during, and after the clinical trial project, more and more competency documentation is required. Having a centralized, trial-specific platform for electronic documentation can minimize skepticism by regulatory agencies, because documentation can be accessed at any time before, during, and after the clinical trial project.

We all know from experience that a well-documented clinical trial can minimize issues associated with regulatory compliance in many areas of study. Conversely, identifying and documenting knowledge-base deficiencies before the investigator meetings, then complementing such documentation with investigator meeting group and individual focus, can prove to regulatory agencies that the clinical trial has been well planned and well organized. Furthermore, immediate and real-time intervention and documentation of trial drift can be continuously achieved as the clinical trial project progresses.
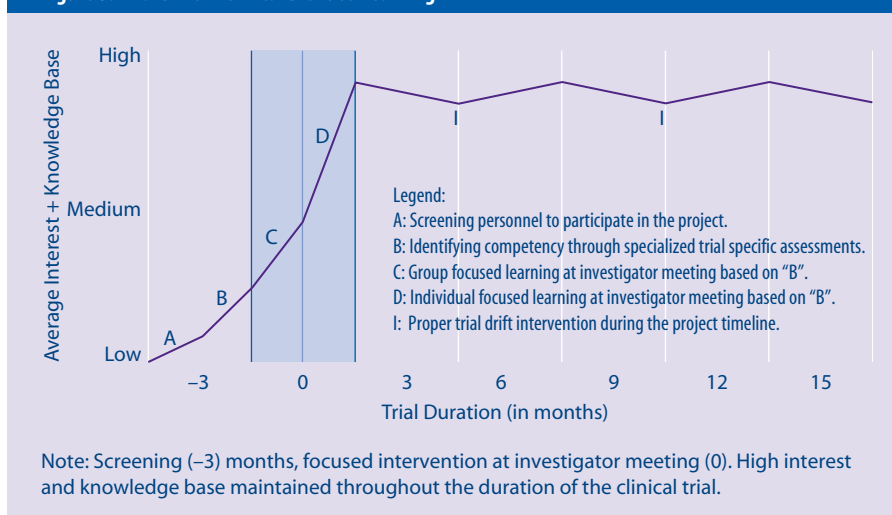
Study Manager, Sponsor, and CRO Benefits

As sponsors demand faster information, intervention, and results at a lower cost, study managers must stay up-to-date with their challenging schedules. Screening personnel, identifying weaknesses, and focusing their education on ensuring that personnel invited to the investi-

gator meeting understand what is expected in the project timelines can make the sponsor, the study managers, and the CRO's jobs much easier.

Investigator Site Staff and End User Benefits

Just as sponsors demand a faster approach to the everyday management of their clin-ical trial, physicians and their staff must also balance their schedules and prioritize their projects as investigative sites and end users look to streamline their efficiencies. The empowerment of end users allows for ownership and a higher value to their project involvement at the local level. The ability to access educational information on a 24/7, on-demand basis, along with the ability to document local competency levels, takes most of the pressure off all parties involved. The ability to access educational documentation on demand at the investigative site, management, and decision-maker levels adds to the lineage of historical competency and up-to-date recordkeeping that is essential in our industry.

Conclusion

A blended approach to clinical trials and research projects can become a good marriage and a great bridge between technology and the more conventional educational approach. This approach is increasingly being embraced in many phases of our industry as we constructively find ways and solutions to combat the trial drift phenomenon. **ACRP**

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