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Trial Drift

Reasons for Failure and Tools for Success

Al Oviedo Pacino II

Most of us working with clinical trials have been frustrated with issues such as staff turnover, missed patient recruiting deadlines, inadequate training, unanticipated needs for issue resolution, etc. Seasoned industry veterans hear these same complaints year after year, but few have been able to offer permanent solutions. However, by understanding the nature of these problems, we can reduce what is referred to as "trial drift."

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. This article examines trial drift, the reasons for its occurrence, and its ramifications on the trial. The article also examines the role education and assessment technologies are playing to better document, measure, and manage the issues surrounding trial drift.

Causes of Trial Drift

Most of us have attended investigator meetings at one time or another. The most obvious clues leading to trial drift include the following:

- improper planning on the front end
- incomplete participation at the initiation meetings
- inadequate training and communication
- competition among multiple clinical trials at the same site
  - more attention to the trials about which staff are knowledgeable
  - limited patient population
- staff turnover at the sponsor, research organization, vendor and/or investigative site level
- failure to anticipate and rapidly adopt to improved technology
- lack of access to productive investigative sites.

Consequences of Trial Drift

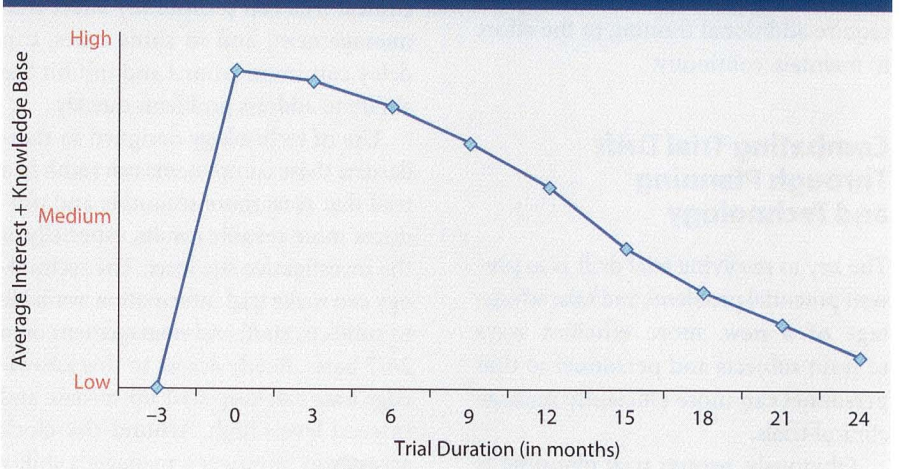
Trial drift in one area of a study can produce a chain reaction that can be difficult to control. Planned study goals can change due to the shift in attention paid to clean ups and fire drills. The inappropriate and inefficient use of technology vehicles for staff education and assessment, especially 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.

Each error introduced may have multiple adverse consequences for the process, each of which can dramatically increase costs.

Regulatory Oversight: Education and Assessment

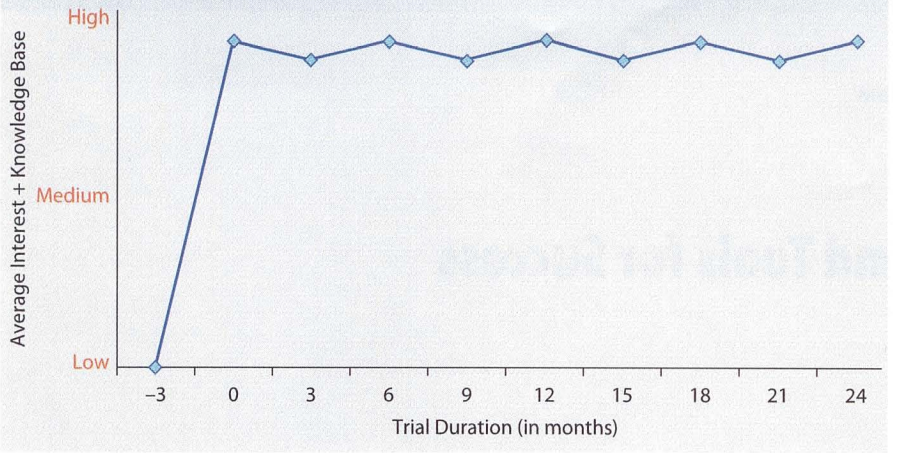
Recognizing the problems associated with trial drift, regulatory agencies are placing more emphasis on clinical trial

Figure 1. Graphical Representation of Trial Drift



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

Figure 2. Graphical Representation of Trial Drift Intervention



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

management, education and assessment, and proper documentation of performed training. The result is a trend toward standardizing the internal processes used to conduct trials.

Regulators increasingly request documented proof that all sites, subjects, and personnel involved in the study have been informed, educated, and assessed and that seasonal re-training be performed, assessed, and documented during the study. In some therapeutic areas, regulatory agencies suggest that inter-rater reliability tests be performed routinely both before and during the trial. They also support standardization of the subject recruiting process. When staff turnover becomes an issue, they may require additional training in the effort to maintain continuity.

Combating Trial Drift Through Planning and Technology

The key to resolving trial drift is to prevent potential problems and take advantage of a new, more efficient ways to train subjects and personnel so that personnel can more efficiently manage clinical trials.

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. For example, a site deemed efficient several years ago may no longer be considered efficient given today's standards in technology and data management. Technology experts often have better information on state-of-the-art technology designed to streamline clinical research processes and, therefore, minimize trial drift.

Knowledge Drift

As the study ages and new personnel as well as new technologies come into play, training needs to be increased to prevent knowledge drift. The inability to assess and benchmark knowledge drift in a clinical trial can profoundly affect trial management, and in some cases, can delay communications and inhibit the ability to address problems quickly.

Use of technology designed to standardize these components can result in a trial that runs more smoothly and produces more reliable results, especially at the investigative site level. The technology can make trial information available to subjects, staff, and management on a 24/7 basis. Ready access to this knowledge base can keep staff up-to-date and interest levels high. Around-the-clock access also improves a manager's ability to recruit patients and manage studies more efficiently.

Today's world is rapidly changing, and the ability to access a trial knowledge base at a moment's notice and from anywhere in the world can profoundly affect the ability to meet recruiting deadlines, meet study budgets, and ultimately produce a successful study.

Online Web-based training as well as video-assisted teleconferences also offer affordable training to geographically dispersed groups and can be organized in smaller, bit-sized segments to minimize disruption to daily work schedules.

However, not all platforms can provide solutions that can be adapted to meet the specific needs of a clinical trial. It is vital to select a provider experienced in working with the complex clinical trials industry and trial drift phenomenon to adequately improve training and communications among sponsors, vendors, and investigative sites.

The technology should offer the opportunity to benchmark data for analysis and refinement. Study managers must be able to assess the skill level of all parties involved in a study at a moment's notice, to address trial drift issues before they affect results. Managers should not be forced to wait months, weeks, or even days for site analysis information that would allow them to administer an intervention plan.

Conclusion

Trial drift is a complex and evolving phenomenon that has expensive consequences if it is not properly managed. Current technologies offer a solution to trial drift.

Al Oviedo Pacino II is a senior executive with more than 15 years' experience in the healthcare and clinical research industries. As an entrepreneur he has held multiple positions with well established CRO and technology companies within our industry. He is the founder and current President of Hillicon Training Campuses. Mr. Pacino is the current vice-chair of education for the ACRP data management forum and has extensive experience with standardization and the internet delivery of training and assessment content and Medical Scales commonly used in clinical trials. He can be reached at alpacino@hillicon.com.