

The Impact of Strategic Communication on Clinical Trial Performance

A FIRECREST CLINICAL WHITE PAPER

INTRODUCTION

Clinical trials today are more complex than ever before: unique procedures per trial protocol have increased 46%; total procedures have increased 65%; and the number of clinical trial days is up by 70%. Despite these complexities, the pharmaceutical industry has been remarkably reserved in adopting new information and communications technology. On the majority of clinical studies, there is still an over-reliance on paper-based Case Report Forms (CRFs) as the primary source of data capture with a subsequent manual upload of data to EDC systems. At present, approximately 75% of all clinical study data is captured in this manner, creating a cumbersome paper trail, which inevitably results in workflow and cost inefficiencies. The industry is in acute need of a Point of Care medium of capturing this data.

Poor clinical trial performance resulting from the combination of poorly designed principal investigator meetings, ineffectual training methods, monitoring issues, and inadequate global communication may be responsible for preventing approximately 50% of life-changing therapeutic compounds making it to market. When the failures lie not in the compounds themselves but in the clinical trial processes, it is essential to adapt existing methodologies in order to ensure the success of critical Phase III studies.

One of the most useful aspects of the Internet is that portals can be created for a specific purpose, such as for the conduct of a particular clinical trial. In a global environment and a digital age, outdated patient recruitment, training, and communication methods simply don't meet the needs of today's complex clinical trial designs. The answer lies in an overarching system enabling centralized trial management, point of care and role-specific training, and electronic data capture, as well as instant global communication and 24-hour user support.

SPECIALIZED NICHES

The investigative landscape is well-populated with companies offering piecemeal solutions to niche areas within the clinical trial structure. *Examples include:*

- Web-deployed "virtual meetings"
- Interactive Web randomization systems
- Web-based patient event report diaries
- Study communication websites
- Web-based secure document exchange
- Electronic CRFs
- Web-based recruitment aids
- Electronic consent aids

However, the end result of delivering several different technologies to clinical trial sites is that investigators and their site staff must often contend with a plethora of vendor systems, requiring them to train on several technology platforms, with separate logon information and ultimately different end-user functionalities. None of these individual solutions effectively encompass the needs of study sites because their design is not based on an overall site performance model, but rather focuses on a specific area of the clinical trial process.

STUDY PORTAL

The solution to the communication problems within clinical trial starts with the creation of a Web-based study portal where all of the trial information can be centrally stored, regularly updated, and made strategically available to all global study personnel from an investigator at a remote trial location to the study team and corporate sponsor personnel.

This study portal is a central repository for protocol-specific, role-based training modules, essential trial documentation, and step-by-step, point-of-care procedural information. With mobile technology enabling access to this study portal at any time, patient data can be instantly uploaded at individual sites. Live data feeds to the study portal deliver regular updates to all users on patient recruitment, randomization, top recruiting sites, etc. When real-time coordination of study personnel is required, the study portal's online meeting feature can act as an interactive digital meeting site, eliminating the need for travel.

Exceptional end-user experience and ease of use is essential in guaranteeing an acceptance of this technology by sites. The study portal can be visually and conceptually unified so that different aspects of the system deliver the same look and feel; all modules are designed to interact and work in the same intuitive way.

Recent and rapid advancements in mobile technology, such as the Apple iPad, ensure that site staff can now access this wealth of study information as they need it, when they are away from their desktop and by their patients' sides. Mobile devices and applications enable site staff to enter real-time data as they receive it, reducing the dependency on a cumbersome and antiquated paper-based system. The potential for the speed of a clinical study to be increased and the number of careless data errors to be reduced is truly remarkable.

TRAINING

Training for a typical Phase III clinical trial nominally begins with a series of global investigator meetings. These are usually held about six months in advance of site initiation, placing perhaps an unfair expectation on sites to retain and execute training received so far in advance of their actual participation in the study. There are the additional hurdles of language barriers and unimaginative and didactic presentation methods; it's no wonder so little is retained.

On the other hand, great strides have been made in individualized, Web-based training platforms. Information can be presented and delivered in a way that facilitates self-paced training, allowing users to review at will and test their knowledge before engaging with their first patient. Training can be tailored for each role — site manager, clinical monitor, principal investigator and site staff. It can be localized into the user's own language and be sensitive to other cultural differences. Moreover, the beauty of Web-based training is that it can be quickly updated as a clinical trial evolves in line with protocol amendments to individual countries.

The bedrock of clinical trial conduct is that the protocol must be meticulously and faithfully applied, and to this end, it is paramount that training is delivered to sites in close proximity to the date of site initiation. This strategic method significantly improves retention and individual performance in key aspects of the trial.

JUST-IN-TIME GUIDANCE

By combining information from the protocol, CRF, laboratory manuals and other sources, a concise online guide can be created for use by investigators, site coordinators, study monitors and other study personnel.

The system is designed on role-based training delivery, therefore only the information relevant to individual users is presented at specific stages of the study. The guide provides detailed immediate instruction to ensure study procedures are conducted in compliance with the protocol by all site staff and across all study sites globally. Again, participants benefit from receiving information and training when it is most relevant and beneficial, and updates to procedures can be rolled out quickly and simultaneously across all sites. This is particularly valued in complex trials in which dose titrations or the systematic introduction of concomitant medicines is required, for example.

The guide is also the central repository for fundamental reference documentation such as the protocol and operations manual. It is available to study personnel 24/7, 365 days a year and contains the answers to all their study-specific questions.

MONITORING

By improving communications at the site level, compliance, consistency and quality of execution throughout the life of the study is greatly enhanced. Requiring study staff to login to gain access, for example, not only secures data from unauthorized users, but provides the project manager with a record of each staff member's ongoing interaction with the study portal.

Each team member can be tracked to ensure training has been performed and is understood, procedures are followed, timelines are met, and study parameters are maintained. This also allows the study manager to analyze performance on a site-by-site basis — to determine the percentage of sites that have reached a particular milestone, for example — and to guarantee compliance to the requirements set by regulatory bodies.

SUMMARY

Even well into the digital age, the communication taking place in many clinical trials remains a haphazard combination of phone calls, group meetings, email, and voicemail complicated by patient reporting systems like EDC and drug management systems such as IWRS. Investigators know that when trial communications don't — or can't — function smoothly, protocol deviations occur, updates are missed and data is compromised.

The only way to improve the performance of clinical trials — measured by the number of compounds moving beyond Phase III as well as metrics such as improvements in patient recruitment and reduction in data queries — is to reduce the incidence of errors. Achieving excellence in clinical research is possible. The answer lies in a comprehensive system enabling centralized trial management, role-specific training, decision support tools, instantaneous electronic data capture, as well as ease of global communication and 24 hour user support is the only proven solution to improving overall site performance.

ABOUT FIRECREST

Firecrest definitively improves clinical site performance through e-clinical technology solutions that provide investigator training and study management tools. Reducing trial costs and protocol deviation, Firecrest is proven to enhance compliance, consistency, and the quality of execution for all study-related procedures and activities. Firecrest works to increase patient recruitment by 10-12 percent and produces much cleaner data with a 40-50 percent reduction in data queries.