



The Investigator Site Perspective for Ease of Use of EDC

case study



the use of etrials' EDC in a clinical trial led to FDA Approval of the drug

KEY PLAYERS

In the course of conducting clinical trials, there are several key players that have diverse roles and needs but the end goal is the same to conduct and manage a successful clinical trial in the hopes of bringing a new drug safely to market. While the sponsor has the most invested in the trial, study sites and the EDC vendor also contribute to the success of a study. The relationship between the key players is a close-knit one and each are very dependent on each other. The sponsor needs to ensure that the most accurate and up-to-date data is captured and to reach this goal the EDC vendor and study site need to work closely together.

THE SPONSOR

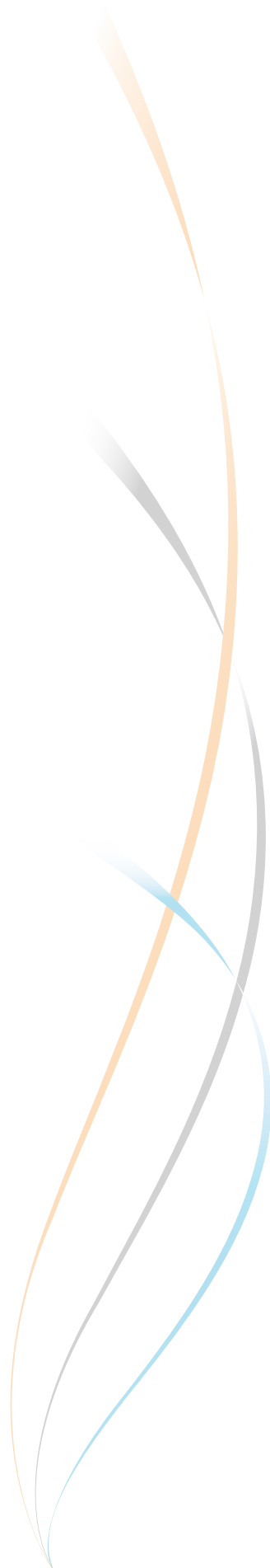
Founded in 1988, the biopharmaceutical company acquires, develops, and commercializes a diversified portfolio of products, including multiple compounds in late-stage clinical development. The Company's goals are to address unmet medical needs and to improve the quality of life for patients. Its products target a variety of disease areas, including overactive bladder, anxiety/panic disorder, stroke, HIV/AIDS, pain and inflammation, serious fungal infections and premenstrual dysphoric disorder (PMDD).

THE SITE

The Site, established in 1985, is a privately owned and independent research facility that specializes in a variety of specialty areas in clinical trials. The Site has successfully completed over 400 clinical trials for more than 70 pharmaceutical and device companies. The Site has conducted Phase I through Phase IV clinical trials in the following therapeutic area: cardiovascular, dermatology, neurology, infectious diseases, pediatrics, urology and medical devices. The Site has over 20 primary investigators, most of which are board certified in at least one therapeutic area. The Site also employs 11 full-time study coordinators that boast over 80 years of research experience.

THE STUDY

The initial Phase III study was conducted at over 55 sites with more than 500 enrolled patients. The objective of the nine-month study was to determine the effects of the drug versus a placebo in the treatment of overactive bladder syndrome. The study parameters include patient randomization and double blinding. There was a follow-up efficacy study conducted at 52 sites with over 600 patients in order to further test the effects of the drug.



The Company has licensed exclusive US rights to develop and commercialize the drug for the treatment of overactive bladder (OAB). OAB is estimated to affect between 50 and 100 million people worldwide and is ranked among the 10 most common chronic conditions. The Company presented the full results from its Phase III trial in April 2003 and announced the submission of its NDA for regulatory approval also in April 2003. The NDA included the results of 32 clinical studies involving over 2,700 subjects and patients.

THE BUSINESS CHALLENGE

With any clinical study, ensuring that the study sites are well trained and equipped to handle the use of an EDC system is essential for the success of a trial. With over 50 sites participating in this Phase III clinical trial, site training was a key element. Typically, prior to the start of a study, an intensive hands-on training session is scheduled to provide in-depth EDC training to the sites. This is a proven and effective means to get sites up to speed and answer any questions before the study is deployed.

Within this study, there were several additional challenges in conjunction with the training process. The etrials team leading the EDC training session had to design and conduct the training via the web after the initial investigator meeting had to be cancelled. The web-based training was of particular concern to one study coordinator who had very little computer knowledge. The study coordinator was not ready to use the EDC system given that the basic she did not have the basic computer skills. Using a computer had to be addressed in tandem with learning to use EDC. And both had to be addressed quickly so that the site was up and running and ready to enroll patients.

ETRIALS SOLUTION

The key to addressing the study coordinator's needs came down to one basic element: the high level of customer support provided by the etrials team. Given this unique circumstance, the goal was to not only provide the necessary support for use of the EDC system but to also ensure that her inexperience with computers did not hinder the progression of the study. There were many calls made to the support team throughout the duration of the trial by this study coordinator. etrials provided the highest level of customer support, including general computer assistance as needed, to give the coordinator a comfort level with both the EDC system and the computer.

METRICS

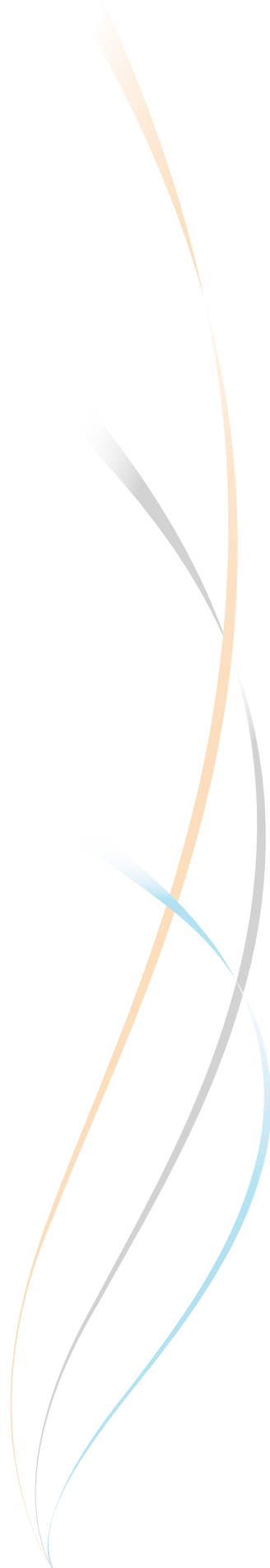
Call volume metrics are useful in measuring ease of use of an EDC system from a site perspective.

Typical call volumes for etrials Help Desk are:

- Average Number of Calls per Month: 164
- Average Number of Calls per Day: 8
- Average Number of Users per Day: 3000+ Globally

Top Reasons for Call:

- Error on Question: 25%
 - Connection: 19%
 - Password Reset: 14%
 - Percent of Calls Resolved the Same Day: 73%
-



In the initial study, the study coordinator placed twenty calls to the Help Desk throughout the duration of the trial. This number is particularly high and not typical of a study given that it originated from one person at one site. Other sites averaged between zero and four calls during this trial. The call volume in this case represented a study coordinator's inexperience with using a computer in relationship to managing a paperless trial.

In the follow-up trial conducted, the support call volume dropped to six calls throughout the duration. The one-on-one training and superior customer service given to the site coordinator throughout the initial study laid the framework for her success in future trials. The site coordinator even mentioned that by the time she attended the investigator training, she was so comfortable with the system that the training was not necessary.

THE BUSINESS OUTCOME

The most significant testament of the success of a clinical trial is the FDA approval of a drug.

In May 2004, the company gained FDA approval of the drug based on review of the clinical studies conducted. The company plans to introduce the drug into the market in the third quarter of 2004. This approval is directly related to the hard work and commitment of etrials to ensure that the sites were successful in their use of EDC.

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