

Monday, Oct 25, 2004

Web-Based CRF Saves WellSpring 30 Percent Over Paper Records*Adapted from WellSpring best practice entry*

Elevated plasma bilirubin (hyperbilirubinemia, jaundice) may be found to some degree in about 60 percent of all neonates. In a small group of children, it may progress to a serious neurological problem termed Kernicterus. WellSpring Pharmaceutical Corp. and Infacare Pharmaceutical Corp. are developing Stanate to reduce bilirubin levels. This drug, Stanate, was discovered by Dr. Attallah Kappas at Rockefeller University and acquired by WellSpring. It was licensed by Infacare from WellSpring, which was contracted by the licensee to perform the clinical research.

To optimize clinical development, WellSpring turned to Target Health to provide an Internet-based electronic case report form (CRF) without having to supply software to each study site. There was immediate cost savings of 30 percent from a paper trial. We also set up an automatic alert system to monitor dosing errors, with the cost of one protocol violation being about \$3,000.

eCRF Implementation

Organization & Project: [WellSpring Pharmaceutical Corp.](#), Infacare Inc. developed and deployed eCRFs for Stanate trials

Technology Vendor: Target Health

Results:

1. Did not have to print and ship paper CRFs to the study sites
2. Eliminated double-key data entry
3. Reduced the number of queries by more than 50 percent
4. Saved time and money since the queries were handled electronically in a fraction of the time of a paper system.
5. Senior management worldwide could review the study status and monitor safety at any time.

The system works as follows: The system administrator creates a study and assigns documents to the study. Since we make sure that the versions are correct, no one can say that they have the wrong copy. When an investigator registers for the protocol, he/she electronically signs a confidentiality agreement. We then review the registration in-house, and consider whether the qualifications of the applicant are equal to the job. Once we approve the investigator, he/she has access to all of the documents needed to support the ethics review process. Once we receive the ethics committee approval, we ship the drug. The CRFs are also online and easily accessible to the study site. All they have to do now is treat the newborn baby and send us the study results.

All data management and study changes were made on the server so that all study sites were synchronized with regard to protocol conduct. Second, a rapid means to report all adverse reactions to all study sites and to management was established through use of an ancillary newsletter, termed 'Biliwatch'. This tool was automatically linked to the eCRF database such that information on Adverse Event as well as enrollment statistics could be automatically updated on a weekly basis and made known to all involved in the study at all study sites.

Unexpectedly, the FDA requested an interim analysis. Under normal circumstances, this would have taken about six months. Without Target E*CRF, the entire drug development process could have been delayed for up to a year. We saved millions of dollars of both direct and opportunity costs. Target Document has allowed us to have one person manage an entire study startup process, worldwide.

We estimate that the overall savings will be more than \$100,000. We will also be able to perform the study with minimal effort and increase revenue by \$500,000. The automation of the clinical trial process has dramatically changed the way we manage clinical trials. While the cost savings are significant, the fact that we are able to see data in real-time is a huge advantage. Reducing the time from data entry to data analysis has allowed us to streamline of the drug development process and facilitate decision-making.