

Logical Ink® Case Study: Clinical Ink's SureSource™ Solution

Tablet-based EDC for Electronic Source in Clinical Trials

Background

There is an overwhelming amount of data that is generated during the course of a clinical trial. Perhaps more amazing than the sheer volume of data generated is the fact that over 65% of all clinical trials still capture, share and store data on paper.

Data is entered manually on paper forms, re-entered manually on duplicate forms and then either entered into an Electronic Data Capture (EDC) system or mailed to the sponsoring pharmaceutical company or contract research organization (CRO). Per FDA regulations, this paper-based system results in warehouses of paper, all of which the sponsor must keep safe and accessible—permanently. The research sites, in turn, must keep their paper records for a minimum of 15 years. Furthermore, since the data is entered multiple times, data entry errors are numerous, requiring the sponsor to send monitors to the research sites (which are scattered all over the country and, quite often, the world) to perform source-data verification.

The industry is making strides toward embracing EDC systems and sharing/storing the data electronically. There are several powerful and popular systems on the market that are gaining rapid acceptance. However, there is one step in the data trail that has not been dramatically improved by these new systems, the initial point of data capture, also called *source documentation*, which documents the interaction with the study participants. Because source documentation is done via paper, it is error-prone, time-consuming and insecure for the sponsor.

The average cost of taking a new drug from test tube to market is already 1.5 billion dollars, with well over 50% of the total being spent on the clinical trial phase. In addition to the cost of running the trial, drug companies are losing an average of 1 million dollars a day in lost revenue for *each day* a drug remains in trials and off the market.

Clinical Ink

Clinical Ink was launched in 2006 to provide electronic source documentation for the research sites, eliminating the problems outlined above with paper-based data collection and reducing the costs and time to market for pharmaceutical companies.

The company was founded by Dr. Thomas Littlejohn, III, M.D. and Doug Pierce. Dr. Littlejohn is the President, Medical Director and co-owner of Piedmont Medical Research Group (PMG). PMG is one of the largest independent research contractors in the United States and has been actively involved in clinical trials for over 20 years. PMG has ten sites throughout North Carolina, South Carolina and Tennessee and has worked closely with all the major pharmaceutical companies and CROs. Doug Pierce is the President and co-owner of Piermed, Inc, a documentation solutions company for the medical community since 1991. Piermed has over 600 customers in 48 states.

The Challenge

Clinical Ink saw the need for an entirely new and revolutionary approach to data collection at the research site. The goal was to eliminate inefficient paper source documents, give researchers a mobile form-factor and provide an intuitive, electronic interface that would be as easy as paper and interface with the sponsor's EDC. Additional requirements were reducing queries by validating the data at the point of capture, providing remote source verification for monitors and capturing cleaner data more quickly for the sponsor.

Deciding Factors

Clinical Ink had very specific requirements for the new SureSource™ system they were proposing. They chose to partner with Logical Progression to develop a solution built on Logical Progression's Logical Ink® digital forms platform for tablet PC. The deciding factors for choosing the Logical Ink® platform are as follows:

As Easy as Paper

First, the solution had to be as easy and intuitive as paper. Clinical research coordinators are accustomed to using paper which requires little to no user training. Unlike many applications that run on the tablet PC, Logical Ink® is pen-friendly and provides a familiar and natural interface with its paper metaphor and handwriting recognition. Users recognize the same paper forms they've been using for a long time, only they are electronic. They can enter the required protocol information, as well as ink notes in the margins of any form.

Regulatory Compliance

The electronic solution had to be compliant with FDA 21 CFR Part 11 guidelines. This included being able to maintain an audit trail of all changes to a form. With the Logical Ink® platform, it is possible to maintain an electronic paper trail of who changed a form and what changes were made. The original ink strokes, as well as the discrete data, are extracted from the templates and stored in the SureSource™ database. The service model also satisfies the FDA requirement that investigators must possess the original source documentation or a certifiable copy at all times. No changes can be made to the source documentation without approval from the investigator.

Accuracy and Reliability

Because SureSource™ is utilizing handwriting recognition as the primary method of data collection, it was imperative that the solution be accurate and reliable. The Logical Ink® form templates and constrained text entry provide 99% accuracy for all data entry. Users can also easily correct data entry errors on the fly.

Form Validation

It was necessary for this solution to significantly reduce the number of data entry errors and invalid enrollment. Logical Ink®'s powerful validation rules implemented in each visit form template eliminate at least 70% of the data entry errors/discrepancies introduced by paper-based solutions. These validation rules are easily created within the form template designer and customized for each study. This "cleaner" data presents real cost savings for the pharmaceutical companies and CROs. Furthermore, rules can outline inclusion/exclusion criteria to automatically notify a coordinator when a subject should not be enrolled in a study.

Mobility

It was imperative that the solution provide greater mobility than traditional EDC solutions that are web-based and require an active connection to the Internet. Clinical trial coordinators perform most of their data collection during the interview with the subjects and they are typically in an exam room, taking vital signs and drawing blood for lab work. Being wired doesn't fit into their natural workflow.

The SureSource™ smart-client developed by Logical Progression can cache visit form data and perform the synchronization with the web portal when it detects a connection to the Internet. This means the coordinator can carry a tablet into the interview just like a clipboard and not worry about whether he/she is connected.

Minimal IT Infrastructure

The solution could not burden research sites with additional IT responsibilities and costs. Many clinical research sites do not have adequate IT infrastructure to accommodate a client/server EDC solution. Logical Progression developed an architecture to support a turnkey ASP model which provides tablets for the sites

and synchronization to a centralized/managed web site. Therefore, the solution does not require the site to provide or manage additional hardware and software. The SureSource™ web portal gives monitors much greater remote access to the source documentation than they could ever have with paper.

The Solution

Using Logical Ink® technology, SureSource™ has the ability to digitally recreate paper forms to match the study protocol requirements, adding verification rules that eliminate the majority of data entry errors, creating a FDA-compliant data trail and allowing for seamless transmission to its web portal and the sponsor. The electronic forms enable the research sites to capture the discrete data using handwriting recognition and also to record the actual pen strokes and signatures. The new system creates both an electronic record and a traditional “paper” trail, ensuring that the data collection process is secure, compliant and transparent.

Once form templates are created, they are loaded onto tablet PCs provided by SureSource™ and sent to the research sites conducting the trial. As subjects are enrolled and visit forms are completed on the tablet, the data is synchronized with the SureSource™ web portal via the Internet. Source documents are made immediately available to a monitor from the sponsor via a secure login. Monitors are able to review PDF images of each revision of a subject’s forms, as well as an audit trail of all changes made. The sponsor’s data management team can download a CDISC-compliant data set, allowing the validated Case Report Form (CRF) data to be imported immediately into its backend system.

Benefits

SureSource™ offers a number of benefits to both the sponsor and the research sites.

Sponsor Benefits:

- Reduction in monitoring costs (estimated 25%)
- Reduction in queries/discrepancies (estimated 70%)
- Reduction in protocol violations (estimated 10%)
- Reduction in time to data lock at end of trial (estimated 10%)
- Consistency of source documentation across all research sites

Research Site Benefits:

- Reduction in invalid enrollment of participants
- More efficient collection of data allowing more participants to be processed per day
- Less time lost to training and troubleshooting problems
- Less expensive and more secure archival of data
- Sites no longer have to develop their own source documentation
- Automatic calculations for data points such as BMI or Drug Compliance

Unlike traditional EDC systems, SureSource™’s digital forms and intuitive web portal allow researchers to conduct their study, capture and then upload the requisite data with minimal training and also provides a significant reduction in errors.

Because the data is originally captured digitally and because the actual form images with pen strokes are retained, there is no need for source-data verification. Presently, the sponsor sends monitors to all the research sites to verify that there is no discrepancy between the source document and the CRF data. The monitoring process accounts for a large portion of the expense associated with a clinical trial.

SureSource™ allows sponsors to cut training time, reduce errors, streamline the enrollment process and drastically reduce the need for monitors. The combination of these benefits will result in significant reduction of costs for the sponsoring pharmaceutical company or CRO. Moreover, SureSource™ offers archival services to the research sites that will enable them to store data offsite in secure servers, allowing

instant access to the data from anywhere in the world and freeing them from the trouble and expense of physical storage facilities.

The benefits to all parties are highly significant. Considering the cost of clinical trials, the efficiencies offered by SureSource™ will result in far-reaching savings for everyone involved.

Technology

SureSource™ takes advantage of the latest Microsoft technology for user experience, mobility, data storage and web services.

Summary:

- Logical Ink® mobile data collection platform for healthcare
- Microsoft .NET 3.0 Framework including Windows Presentation Framework (WPF)
- Microsoft SQL Server 2005
- Microsoft IIS
- Windows Vista and XP Tablet PC Edition

About Clinical Ink

Clinical Ink is a software company specializing in eSource solutions in the clinical trials market. The company is based in Winston-Salem, NC. For more information, visit www.clinicalink.com.

About Logical Progression

Logical Progression is a software company specializing in tablet PC-based electronic data collection and healthcare interfacing solutions. With over 20 years of experience in healthcare, mobile data capture and electronic forms, Logical Progression is an innovator in the healthcare tablet PC market, building ink-friendly and intuitive user experiences. Logical Ink®, the company's core product, is a mobile data collection solution for healthcare that generates an electronic chart of forms pre-filled via HL7 and seamlessly integrates with the EMR without redundant data entry or form scanning. The company is based in Cary, NC. For more information, visit www.logicalink.com.