SureSource™
Electronic Source Record

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 in nearly 100% of all clinical trials the most critical information is still captured and stored on paper.

All research sites capture information about patients on paper records – these original paper records are called source documents and the information within the document is referred to as source data. Per FDA regulations, these paper records must be kept safe and accessible – in some cases permanently. This antiquated process is time-consuming and fraught with errors as the data must be entered multiple times into various systems.

The Challenge: Reduce the Cost
Over the last five years, the pharmaceutical industry has largely embraced web-based electronic data capture (EDC) systems as the preferred means for research sites to input, share, and store trial data electronically. However, the widespread adoption of EDC systems has failed to significantly reduce the cost of conducting clinical research because EDC does nothing to address the most critical step in the data collection process - the initial point of capture with the patient. Because the initial source documentation continues to be done via paper, whether or not an EDC system is used later in the process, data collection remains error-prone, time-consuming and insecure.

Consequently, in an effort to improve quality, research sponsors send monitors to investigator sites all over the world primarily to verify the accuracy of paper records versus the electronic database – this process is called source-data verification (SDV). The monitoring process, and SDV in particular, is the single most expensive component of clinical trials accounting for up to 40% of the total cost of a clinical trial; in total over $8 Billion is spent annually just to monitor and review data at clinical trial sites.

The Solution: The Electronic Source Record—SureSource™
Clinical Ink saw the need for an entirely new and revolutionary approach to data collection at the research site. The goals:

- provide an intuitive mobile technology to capture patient data - as easy to use as paper;
- eliminate data entry errors, the manual SDV process, and unnecessary data queries;
- enable monitors to review site documents/data remotely and more frequently; and
- exchange data seamlessly with any number of clinical systems and databases.

As Easy As Paper
Clinical research coordinators are accustomed to using paper, which requires little to no training. Unlike applications on desktop/laptop PCs, SureSource was specifically built as a tablet PC application and mimics the familiar paper-pen interface. Users recognize the same paper forms they’ve been using for a long time, only they are electronic. Powerful handwriting recognition technology permits users to quickly enter the required protocol information as well as ink notes in the margins of any form. Thoughtful details include the ability to switch menus/navigation based on left/right-hand usage. Importantly, the form factor of a tablet PC, similar to a paper chart, preserves a natural conversational flow - both patients and research
coordinators are used to interacting while information is being written down; using a keyboard/mouse is perceived as a distracting interruption.

**Validated Data**
SureSource inextricably links the electronic form to the database – the only way information is entered into the database is through the electronic form. Consequently there is never a situation where the data on the form is not the same as the database – this eliminates 70% of the data discrepancies monitors discover during the SDV process. In fact, SureSource eliminates the need to perform SDV at all because the forms and data are always the same. Data entry errors are further reduced by powerful validation rules which check the information as it’s entered thereby assuring the data collected conforms to the protocol requirements and is logically consistent. These validation rules are easily created within the SureSource forms designer and customized for each study. This “cleaner” data presents real cost savings by reducing the number and duration of on-site monitoring visits and eliminating much of the time-consuming process of resolving data discrepancies.

**Remote Monitoring**
Currently, even though patient data is entered into the study database it can take many weeks before a monitor visits a site to review the original source documents and validate the information. With SureSource, the database is always in a validated state – by definition there are no discrepancies between the electronic forms and the database. Furthermore, PDF images of the original electronic forms are available immediately to be reviewed over the internet. This enables monitors to review the information for clinical/medical issues not simply to manually check for data errors. Consequently, monitors use their expertise to focus on the overall context not just data errors, review information more frequently, and do so without the costly expense and significant time burden of traveling on-site.

**Mobile Technology**
Clinical trial coordinators perform most of their data collection during in-person visits with subjects. Typically this occurs in an exam room but could take place across town at a nursing home, a hospital, or wherever else the subject might be. A mandatory 100% connection to the internet simply doesn’t fit into the natural workflow. The SureSource application stores information locally and synchronizes data over the internet whenever it detects a connection – consequently coordinators need not worry about connectivity.

**Regulatory Compliance**
SureSource is compliant with FDA 21 CFR Part 11 guidelines – in fact, by capturing information electronically, for the first time there is a genuine audit trail of the source documentation itself. The audit trail includes all changes to a form: who made the change, the date/time, the previous versus current values, and all other activity done within the application – even viewing a form is logged as an event in the audit trail. The original ink strokes, as well as the discrete data, are extracted from the templates and stored in the Clinical Ink database. The service model also satisfies FDA requirements 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 authorized site personnel.

**The Process**
SureSource is as easy to deploy as existing EDC technologies. However, rather than create electronic case report forms (which capture only a subset of patient data), Clinical Ink creates
electronic source documents that comply with Good Clinical Practice guidelines, the study protocol requirements, and FDA regulations.

Step 1: Create electronic source documents including data verification rules
Step 2: Create central database environment to store and transmit patient data
Step 3: Train site/monitor/sponsor (by role) to use SureSource tablet PC and web portal
Step 4: Provide user support and data hosting/transmission during the study
Step 5: Create final site-specific document/data archive files at conclusion of study

Throughout the study, Site personnel routinely enroll patients by creating a new chart (which includes all of the source documents for the study) and check-in/check-out existing charts from the central server each time the patient returns for a new visit. Monitors and Sponsors review patient source documents from the web portal and can review the version history and audit trail if necessary. Monitors and Sponsors can also run reports, including performance metrics, as well as schedule data transfers in a variety of standard formats.

Benefits
SureSource offers clear benefits to all parties involved in clinical research: Sponsors, CROs, Monitors, and Sites. Unlike many technologies, the cost saving benefits are easily quantified. Specifically, monitoring costs are dramatically reduced by reducing the frequency and duration of on-site visits and eliminating up to 70% of data queries (those related specifically to discrepancies between source documents and data).

Sponsor/CRO Benefits:
• Reduce monitoring costs by 25-30%
• Reduce data queries/discrepancies by 60-70%
• Immediate access to validated data - no waiting for manual on-site SDV
• Consistent source documentation across all research sites; better protocol compliance

Research Site Benefits:
• Data captured at time of patient visit; Eliminate duplicate data entry & errors
• More time to focus on patient recruitment and patient visits
• Reduced training time and greater ease-of-use as compared to EDC
• Eliminate paper archival and retrieval costs/processes

Monitor Benefits:

Technology
Clinical Ink takes advantage of the latest Microsoft technology for user experience, mobility, data storage and web services.

Core application technology:
• Mobile data collection platform specialized for healthcare (Logical Ink SDK)
• Microsoft .NET 3.5 Framework including Windows Presentation Framework (WPF)
• Microsoft SQL Server 2005
• Microsoft IIS
• Windows Vista

SureSource is designed to run on Intel-based processors that have been optimized for the specific demands of clinical research. This includes components designed for speedy
application response (including handwriting recognition), longer battery life, and reduced heat/noise output as compared to most standard computer configurations.