Beyond EDC: Resolving Data-entry Challenges faced by Electronic Data Capture Systems in Clinical Trials

A White Paper

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The Problems with EDC

Electronic Data Capture (EDC) systems have swept the Clinical Trials industry in recent years, promising to transform the drug development process. Most EDC systems are browser based and many operate on a Software as a Service (SaaS) model, with remote hosting capabilities. It is estimated that nearly half or more clinical trials today are run partially or fully on EDC systems[1], eliminating paperwork and other inefficiencies in the process.

However, interim reports from a recent survey conducted by the eClinical Forum[2] ("Investigational Site Perspectives on Clinical Trial Information Systems,") show that the use of paper case report forms (CRFs) is rising, even as EDC adoption is increasing. According to a Clinpage report[3], clinical trial site staffs believe that EDC system use is forcing them to spend *more* time working on trial data, not less. According to the survey, 46% of respondents reported having to do more work due to EDC, compared to 23% 8 years ago[3].

Another problem in the use of EDC systems found in the survey was "that EDC systems typically don't have the trial data until 48 hours to a week after it is written down by hand or collected in some other system, despite contractual obligations to provide the data entry within shorter time windows. (Some sites and sponsors report much longer lag times.)[3]" Part of the reason for this could be the natural workflow of healthcare professionals, which involves capturing data in a pen-based manner while in front of patients. The aversion to keyboard-based entry into a computer during a patient contact is a common theme, even outside clinical research.

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[1] Bio-IT World. http://www.bio-itworld.com/EDC-Adoption.aspx?terms=health
[2] eClinical Forum. http://www.eclinicalforum.org/main/Home/tabid/36/Default.aspx
[3] Clinpage. "More paper, more burden." http://www.clinpage.com/article/more_paper_more_burden/C5

To illustrate this point the Clinpage report mentions that, "In 2001, the last time the survey was conducted, 16 percent of respondents said study data was initially entered from a paper CRF; in 2009, that number rose to 26 percent. Also in 2001, 66 percent of the data was initially entered into a paper patient file. Eight years later, that number had increased to a bit more than 71 percent.[3]" Several sites have also found the training requirements to use EDC systems to be onerous and have had to rely extensively on support desks slowing down user adoption in the intended manner.

BeyondEDC™ – The best of both worlds?

Despite the limitations of EDC systems listed above, they have certainly improved the efficiency of data collection and clinical trial operations. However that is not sufficient to change the preferred workflow of most clinical professionals. There is a need to accommodate the pen-on-paper-based workflow of these personnel and integrate it with the data repository & management function of an EDC or Clinical Trial Management System (CTMS).

In recent years several technologies have been developed that address this issue and could serve as a good complement or substitute for EDC systems. These are point-of-contact data collection systems using devices such as the Digital Pen, Tablet PCs and more. These devices allow the user to input data using a natural pen-based workflow.

Based on technology from a Swedish company called Anoto[4] the Digital Pen looks and feels like a regular ballpoint pen. Unlike regular pens, the Digital Pen contains an integrated digital camera, an advanced image microprocessor, and USB connection or Bluetooth wireless capability. Users write with the Digital Pen on paper which contains a nearly invisible and unique to every page dot pattern in the background. The camera takes digital snapshots while the user is writing, capturing enough data to determine the exact position of the pen, what it writes or draws, the time each pen stroke was made, as well as on which particular paper form writing occurred. All of this data is then retained in the pen's memory as a series of coordinates. The pen can store many pages of handwritten data at a time. Once the user has finished writing, the pen can be docked to a PC where the data can be downloaded and processed by special software with handwriting capture and processing capability (by docking the pen to charge each evening, data collection is uploaded, supporting entry of eCRF data within 24 hours). A new Digital Pen, the LiveScribe[5], allows not only the recording of handwriting but also audio. This unique combination of capabilities poses strong potential for high utility in healthcare applications where handwritten and dictated notes are preferred.

[4] Anoto. http://www.anoto.com/
[5] Livescribe. http://www.livescribe.com/

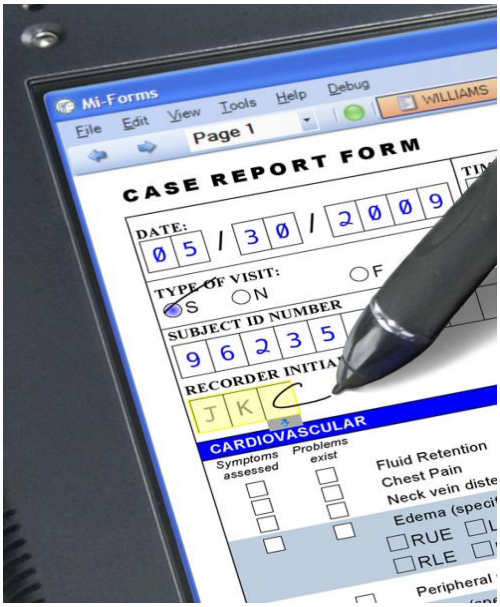
A Tablet PC is a notebook or slate computer with a special digitizer screen which allows users to naturally handwrite with a pen-like stylus. These computers, available from Dell , HP , Equus, Lenovo and others, are commonly available in the commercial market and run Windows 7, Windows Vista or XP Tablet PC Edition. Lighter and more versatile than ordinary notebook computers, they are designed for mobile use by professional personnel in many industries including healthcare. Convertible tablets include full keyboards and have a screen which swivels and locks down for mobile handwritten tablet input. Slate tablets do not have a physical keyboard by default but do include a "virtual" keyboard where letters and numbers can be tapped out if needed. Using a Tablet PC with wired or wireless Internet connection allows a form to interface with the database to import demographics using abridged information (such as entering the subject number only) and selecting "Lookup," for pre-defined parts of the form to be auto-populated from the appropriate fields in the back-end database.

Mi-Forms for Point-of-Contact Data Collection

Point-of-contact data collection devices, such as the ones listed above, are only as functional as the software systems that power them. Having 10 years of experience in pen-based data collection technology and software, Mi-Co[6], a Durham, NC-based software company is able to

[6] Mi-Co. www.mi-corporation.com

provide a user-friendly, flexible and powerful technology platform called *Mi-Forms* to enable pen-based, real-time, accurate point-of-contact data collection.



Pen-based data collection: Mi-Forms in Action on a Tablet PC

Mi-Forms has uses in a variety of applications for clinical research including e-Case Report Forms (e-CRFs), Informed Consent Forms (ICFs), Adverse Event (AE) reporting, Site Monitoring Reports, Registry Data Collection, e-Patient Reported Outcomes (ePRO) and more. Health Decisions International (HDI)[7], a Durham, NC-based CRO and Mi-Forms user, has compared the use of Mi-Forms for e-CRFs versus Fax-based systems and EDC systems across more than 15 clinical trials. HDI found that Mi-Forms enabled data to be received into the database much more quickly, within 24 hours, and produced far fewer queries (see table below).

[7] Health Decisions International. http://www.healthdec.com/

EDC Method	Queries Per 100 Fields
Digital Pen or Tablet PC	**1**
Faxback Systems	**4-6**
Web-based EDC	**7-8**

In addition, a large Orthopedic Medical Device company that has also used Mi-Forms for e-CRFs on Tablet PCs and compared 5,000 CRFs processed via Teleform (a faxback system) to 5,000 e-CRFs with Mi-Forms. They found a 60% discrepancy rate with Teleform versus an error rate of *less than 1 %* with Mi-Forms (17 out of 5,000), due to the live-edit checks built into MiForms.

"Despite recent efforts at electronic data collection (EDC) in the industry, an ongoing difficulty continues to be collecting data in a way that does not interfere with patient interviews. Although technology is in the forefront of drug development, sometimes doctors prefer old fashioned things because it works better for them. Clinicians often find that EDC is impractical, often actually hindering their work because they are used to the ease of keeping notes on paper. The Mi-Co approach combines the ease of dealing with paper with the ability to immediately process and transmit data as they are collected from patients. The resulting hybrid system is considerably easier than either paper or electronic systems and has not been offered before in this industry." **Michael Rosenberg, MD, MPH, President and CEO of Health Decisions. 2002**

Large academic medical centers such as The University of North Carolina at Chapel Hill, Duke University and Indiana University School of Dentistry have all used Mi-Forms solutions in large clinical trial settings and found considerable benefits in reduced errors, and quicker submission of data into the system. Clinical sites and end-users have also expressed great satisfaction with the ease of use of the technology and the short learning curve required to adopt it into their regular workflows.

> "We've simply replaced pen and paper with digital ink and Tablet PCs. With this change, we're now in a position to collect an entire spectrum of data and deposit the data simultaneously in a clinical system or a national registry. At the Medical Center we can now even send images of forms to our Electronic Medical Record (EMR) System saving a number of steps in that process. It's like zapping your paper form right into the database." - **Dr. Richard Shaw, Director of Research, Quality and Education for the Sutter Pacific Heart Centers of Sutter Health**

Mi-Co provides a novel paper-like user interface software technology that supports Tablet PCs by presenting an image of a paper-style form on which the user writes, and performing edit checks and business rules validation as the user writes. The software presents a user interface that is like writing on paper. Users may correct or make changes simply by writing over top of incorrect characters. The freeform fields allow for capture of notes, comments, diagrams, and signatures. Audio recordings, photographs and other multimedia can also be attached to the e-form on the Tablet PC before exporting the data. Mi-Forms for Digital Pen provides elegant interfaces to print dot-pattern paper and recognize handwritten text, and it allows recording of data without redundant double-key re-entry from paper forms to electronic EDC systems.

Summary

EDC systems have taken Clinical Trials a long way from the days of paper-only processes. However, given the preferred pen-based workflow of healthcare professionals, lack of adoption and user difficulty are common challenges posed by the use of such systems, which at times results in more time and paper, as shown by several studies. One potential solution involves going beyond EDC to incorporate the preferred pen-based workflow into the data entry process for easy adoption, and accurate, real-time data. Mobile devices such as Tablet PCs and Digital Pens provide such an avenue and software platforms such as Mi-Forms from Mi-Co power these devices, making the collection and management of data easy, accurate and efficient. In addition, as the use of these devices within physician office practices grows, major incentives (and possible penalties) may result if offices do not leverage an electronic system. Offices will be using similar technologies for electronic medical records, and many have already started the transition – why not use technologies to support workflows and the current ways of doing business now, thereby easing adoption and supporting your technology objectives?

About Mi-Co:

Mi-Co is the developer of Mi-Forms Digital Ink handwriting recognition and data cleaning technology and provides solutions for smart e-Forms data collection in a variety of industries including clinical research. Mi-Co's enterprise Mi-Forms Software System enables flexible forms design and the capture, handwriting recognition, validation and automatic communication of forms-based data from handwritten source documents. Mi-Forms supports enterprise data capture using Tablet PCs, the Digital Pen, Pocket PC, and signature capture devices, and has been validated for 21 CFR Part 11 compliance. Mi-Co is headquartered in Research Triangle Park, North Carolina. For more information on Mi-Co, please visit www.beyondedc.com.