
DataFax and the Digital Pen

Our use of the digital pen in an in-house trial

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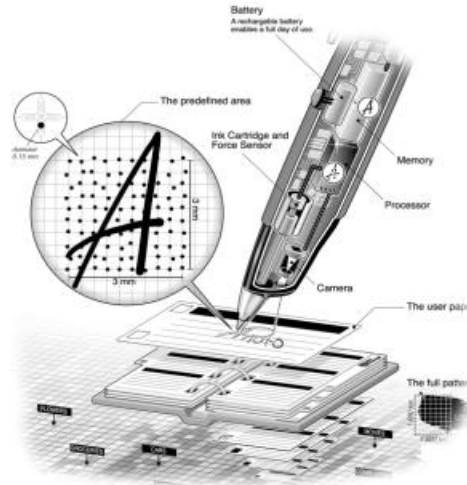
Digital Pen & Paper

Background

- Presented at DFUG 2002 by Henrik Bergknut of Clinical Data Care
- Originally developed by Anoto, now being developed for various uses in North America by HP
- It is a Pen and Paper Technology that allows a special pen fitted with a camera to capture, remember and communicate precisely what, where & when it has written on any set of pages printed with a special pattern

DataFax & Digital Pen Integration

The technology behind our recent in-house trial of the digital pen.



- Modified PDF files of CRFs were created and then registered in a Digital Pen and Paper server.
- Forms were printed in-house on an HP color printer.
- CRFs were completed by a group of volunteers using the digital pen.
- Pen stroke data was uploaded from a laptop to the DPP server.
- All pen strokes were automatically overlaid onto CRF background and e-mailed into DataFax.
- Data entry proceeded as usual.

System Components



- Pen produced by Logitech
- Pattern developed by Anoto
- Print-on-demand developed by Advanced Solutions Lab (ASL) at HP
- Windows XP laptop uploads data from pen over analog phone line (deployed at the clinical site).
- Windows 2000 DPP server running SQL Server associates pen strokes with forms (in-house).
- Internal e-mail used to mail forms from DPP server into standard DataFax set-up

In-house Trial Protocol

- Volunteer subjects from ALZA were recruited to transcribe data on to CRFs using the digital pen
 - Subjects were “digital pen naïve”
 - Data transcribed was representative of typical study data
- Pen data was compared to data from previously faxed forms

Some Positive Observations

- DataFax’s ICR improved with digital pen images
 - Cleaner images, no skewed images
- Feedback from data entry personnel was very positive
 - Images were more consistent, easier to enter from
- Form by form comparisons and database listings indicate that the system is reliable

Some Problems

- The laptop user interface was not intuitive enough
 - The interface needs to be simplified
- Using the digital pen is not quite “just like using a regular pen”.
 - Each form has a “send box” and data will only be sent if the send box is checked...this is true for every form. The requirement of checking the send box on each form is the biggest drawback to the system
- Many fax machines, especially newer machines, transmit the Anoto pattern as unwanted background noise, interfering with fax legibility

Some Potential Problems

A list of problems we would expect in a ‘real trial’

These are problems we didn't see in our in-house trial along with some ideas we have about dealing with or preventing them.

- Problem: A regular pen, instead of a digital pen, is used to fill out a form (or part of a form).
 - All forms will continue to be bar-coded so that they can be faxed if necessary
 - Non-standard ink colors in pens may be used to aid in compliance & monitoring.
- Problem: A digital pen is lost before its data can be uploaded.
 - The paper is still regarded as the original source and the form can still be faxed – no data is lost.
- Problem: Users can forget to check “send box” on a form
 - The digital pen remembers all pen strokes, even when the send box is not checked – so data is not lost, only delayed until box is finally checked
 - The visit map and edit checks will continue to be powerful tools for assuring, just as they are with faxing, that forms arrive when they are supposed to

The Big Question

Why use the digital pen instead of faxing?

Reasons to Move Forward

Why we are continuing to look at the digital pen

- It will provide us with cleaner images
 - Data entry should be easier, fewer images re-sent, better images for submissions, better ICR, etc.
- It should lead to more timely data, particularly once it transitions to wireless
- It is an EDC solution that integrates well with our current processes
 - We can continue to use DataFax
 - We can make decisions about when to use the pen on a study by study basis
- Further integration of its own built-in ICR technology with DataFax should lead to improved number and *text* ICR support

Our Next Steps

- We are planning to use this in a single site PK trial this year
- We are exploring how we can integrate the pen's ICR technology with DataFax
- We are talking to HP about wireless pen technology and additional system changes that will improve fax quality and user acceptance