



Accelerating information flow in clinical trials

FACTS

Customer: *writeresult*, a provider of data management solutions for clinical research to the pharmaceutical/life sciences industry, based in Cranford, NJ.

Challenge: Capturing patient-reported outcomes during clinical trials has traditionally been administered using pen and paper forms. This method resulted in diminished data quality, data loss and inefficiency due to the need for data transcription. Pharma companies needed a cost-effective solution that could digitize the data being captured and be simple to train sites and patients to use.

Solution: *writeresult* data management solutions enabled by the EDW® Platform solution provided by ExpeData® leveraging Anoto Digital Pen and Paper technology.

Benefits: Digital Pen and Paper technology required minimal training for clinical sites and patients participating in studies. The solution interprets the handwriting with high accuracy and provides an image of the completed forms accelerating the flow of information to the sponsor. This has enabled the sponsor to leverage the efficiencies of electronic data capture while preserving the simplicity of pen and paper.

“Digital Pen and Paper technology has proven to be our most intuitive method of collecting PRO data across different therapeutic areas and patient populations...”

Dennis Salotti, DO, *writeresult*

Background

writeresult provides data management solutions for clinical research. Their focus is intuitive capture and management of electronic patient reported outcomes (ePRO) data, which documents information about a health condition and its treatment. With users in the thousands, including site personnel, nurses, physicians, patients and supporting staff, *writeresult* has demonstrated that the digital pen ePRO solution is efficient, accurate and easy to use.

PRO questionnaires are used to measure multiple aspects of how a patient experiences a health condition or treatment, such as how a patient feels while experiencing a condition or how they function during the study treatment. These questionnaires are designed for the patients to complete themselves without influence from other parties.

Historically, PRO responses were completed by the patient on paper and sent to the clinical data entry department for double-key entry. *writeresult* needed to find a data capture solution that would speed up the processing and sharing of the data globally while preserving the ease and simplicity of data collection using pen and paper.

Such a solution would need to meet a variety of factors such as:

- Being intuitive for patients to use with little or no computer experience and for those with limited manual dexterity
- Increasing speed and efficiency of data capture and easily digitize information
- Being simple to implement at clinical sites and cost effective for sponsors

Choosing the right solution

writeresult reviewed multiple forms of electronic means of capturing patient-reported outcomes. This included data capture via PDA/smartphone, Interactive Voice Response (IVR), and Interactive Web Response (IWR). They determined that while all are appropriate for certain uses, they needed a solution that would be universally intuitive for patients and sites without sacrificing the efficiency of electronic data capture.

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How it works

A camera and pressure sensor in the pen record the way the patient writes each stroke to facilitate automatic interpretation of the responses. Information is captured in the pen's memory. The pens are rechargeable and have enough memory to store many PROs before the investigational site transfers the data to data management.

writeresult provides client sites with Anoto Digital Pens and PRO assessment forms printed by *writeresult* using the ExpeData software platform. The PRO assessment forms are provided as professionally bound case books containing all of the assessments required for the study, separated by tabs for the appropriate visit and timing for performance of the assessment. Upon participation in the clinical study, the patient is provided with a digital pen and the appropriate forms for the patient visit and asked to complete the form as they normally would with a regular pen and paper.

At completion of the visit and the associated forms, the study coordinator docks the digital pen to the PC and transmits the data to *writeresult* for data processing.

"Digital Pen and Paper technology has proven to be our most intuitive method of collecting PRO data, across different therapeutic areas and patient populations," said Dennis Salotti, Director of Operations at *writeresult*.

Deploying the technology

writeresult currently has 1,250 digital pens in active use at sites around the world, with another 300 in process of being issued. *writeresult* clients are given a CD containing ExpeData software for transferring the data from the pen. Once this software has been installed, the study coordinator can easily transfer data to their data management group where verification and cleaning occurs. All the investigational site needs to do is plug a pen 'cradle' into the USB port in their computer, and insert the pen into the cradle. The data will automatically transfer from the pen to data management via the Internet. High-speed Internet access is not required; this is helpful in global studies where only dial-up access is available.

All transferred handwriting is automatically interpreted using the latest handwriting interpretation software. Numeric, alphanumeric and checkbox fields can all be interpreted. Even visual acuity scales (VAS) can be measured

automatically by the system. The interpreted responses are automatically merged with their corresponding PRO form template, enabling the PRO image to be viewed by the clinical data coordinator (CDC). The data is stored in the database within minutes from anywhere in the world. All interpreted responses are 100% human-verified by the *writeresult* data management team. If there are any values that are not legible, the CDC can query the site for clarification or correction.

The *writeresult* data management solution is comprised of:

- Anoto Digital Pen and dot pattern technology
- ExpeData software for transferring data, printing forms/books and data processing
- *writeresult* full service clinical data management from initial planning to final database lock
- *writeresult* project management and supply logistics for all digital pen and paper supplies
- 24/7 online access to digital image of completed forms

Benefits:

- **Time savings** – It is fast and easy for the sites to use and transfer data. Final cleaning by data management is simple and quick.
- **Increased consistency of patient measurements** – Measured responses such as visual analog scales (VAS) are systematically measured by the ExpeData EDW Server reducing variability within and across investigator sites; eliminates risk of transcription error compared to regular paper and pen.
- **Easy to use** – This natural writing interface also better suits patient population (e.g. a patient with pain, dexterity issues). Since the technology is simple to install and use, it is not intrusive to the staff's daily work.
- **Durability** – The pen is sturdy, unlike a laptop or tablet that breaks easily if dropped.
- **Better efficiency** – With Digital Pen and Paper technology, sites can see the PRO forms via the Internet moments after data transfer.

Partner profile

Headquartered in Miamisburg, Ohio, ExpeData is an innovative software company and a global leader in digital writing. The award-winning EDW@ solutions bring a new dimension in workflow efficiency, as handwritten input captured in the field is instantly transformed into actionable digitized data, ready for immediate use by business systems. The solution supports both Digital Pen and Paper technology and the latest generation of tablets devices. Digital writing delivers significant benefits to organizations of all sizes. EDW solutions are used across the globe, delivering value in multiple industries including Field Services, Financial Services including Insurance, Healthcare, Pharmaceuticals and Clinical Research, Logistics and Transportation, Government and Public Services, and Utilities.

www.expedata.net

Customer profile:

As a Data Management CRO, *writeresult* has been conducting research studies with Digital Pen and Paper technology since 2004 as one of the early adopters. Initial efforts were focused on research in Food Use Product Safety studies, for submission to the EPA in a process that parallels Drug Development and the FDA. By 2006, *writeresult* was partnering with pharmaceutical companies to apply this novel technology to Clinical Research. The *writeresult* solution has been proven to provide clean, usable data in a manner consistent with industry timelines and processes, in a format suitable for marketing applications.

www.writeresult.com