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Digital Pen and Paper technology helps accelerate clinical trials

Captures handwritten clinical data electronically, quickly and securely to save time and cost in drug discovery process

Lund, Sweden – The ongoing challenge in drug development and clinical trials is to capture and document data accurately. The goal is to complete the process of viewing, cleaning, analysing and coding the data as fast as possible, ultimately with the goal of bringing a fully-tested new drug to market quickly.

With clinical studies often taking anything from several weeks to years to complete, vast amounts of data need to be collected. Traditionally, this data had to be entered manually into IT systems for further processing and analysis. Digital Pen and Paper technology from Anoto has been shown to significantly speed up the capture of trial data, and help accelerate this process.

Digital Pen and Paper automatically converts handwritten notes in clinical trial forms into keystrokes, avoiding the time-consuming manual data entry altogether.

The digital pen looks like a ballpoint pen. A tiny infrared camera at its tip tracks its movements relative to a grey dot pattern printed on the form, recording and storing what is being written. When investigators have finished gathering data, they place the digital pen into a USB docking station to synchronise the pen with backend IT systems. Alternatively, data can be transmitted via a Bluetooth-enabled mobile phone. As a result, clinical trial data is available immediately for processing and analysis.

No changes to workflow

The greatest advantage of the technology is that handwritten information can be digitised without any changes to existing work routines, and that a high level of data accuracy can be achieved. Users continue to fill in forms with a pen, as before. In this way, the advantages of paper are retained, for instance its ease of use, the ability to archive information easily and its original content, which is often needed for legal purposes. Likewise, users do not have to be trained to use tablet PCs, PDAs or scanners.

This in turn means that Clinical Research Organisations (CROs) can realise time and cost savings, as well as avoiding manual data entry errors. Studies have shown that digital data capture using Digital Pen and Paper is superior to alternative solutions such as laptops, PDAs or tablet PCs. Data entry error rates are close to zero, all while realising time savings of up to 60 per cent. This was confirmed by a study published on the occasion of the World Usability Day 2008 (Boldt R, Raasch J, Hamburg 2008).

Anoto technology at EuroDIA 2009

As the inventor of Digital Pen and Paper, Anoto makes its technology available to a worldwide network of partners who design tailored, industry-specific Digital Pen and Paper solutions.



In the pharmaceutical sector, the technology has a proven track record in areas such as the collection of patient data and documenting the progress of clinical trials.

At EuroDIA in Berlin, Massimo Raineri, Head of Systems Development, Biometry, **Actelion Pharmaceuticals** (www.actelion.com) is chairing a conference session at 9-10.30 on Wednesday, March 25th entitled "*A look into the future: what is on the horizon after we have managed EDC properly?*" (Hall 9). His own presentation will be looking at the use of Digital Pen and Paper technology for data collection in clinical trials, which Actelion has been pioneering.

The following Anoto partners will be exhibiting their solutions at the show in Berlin:

Kayentis (www.kayentis.com), an Anoto Platinum Partner, will present its Clin'Form solution (Stand 1277, Hall 12). Clin'Form, which is based on Anoto technology, provides an easy data collection method for sponsors, investigators, Clinical Research Associates (CRAs), patients and other parties involved in clinical trials. It offers a high level of data quality combined with all the advantages of electronic data management, significantly streamlining clinical trials costs. Clin'Form has been adopted by more than a dozen pharmaceutical companies and has been used with more than 50,000 patients in 50 countries and in as many languages.

PharmaForms GmbH (www.pharmaforms.com), a supplier of clinical trial documentation such as Case Report Forms (CRFs), patient diaries and submission dossiers, is showing its dotforms–eCRF system (Stand 1248, Hall 12). Based on Anoto's technology, this solution aims to automate clinical data capture completely, from the CRF all the way to the database. Dotforms-eCRF has been certified for use in the pharmaceutical sector. The Anoto technology combines the usability of paper with the flexibility of information technology. Investigators and patients continue to write on paper as usual, using a digital pen. PharmaForms provides the paper forms, which look just like normal CRFs but feature the Anoto dot pattern. Data recorded by the pen is transmitted to backend IT systems and available for analysis and reporting in real time. Dotforms-eCRF is already in use for clinical trials in 20 countries, with several hundred pens deployed.

Belgian solution provider **Arco/eClinics Solutions** (www.arco.be - Stand 1202, Hall 12) is highlighting its DocGenerator system that helps create documents based on Anoto's technology on top of a powerful in-house document and workflow management system. This combination enables the trial sponsor to build flexible data capture and management workflows, tailored to a wide range of needs and processes. The latter can include Optical Character Recognition (OCR), customized quality control and validation as well as reporting. The solution combines the advantages of pen and paper with real-time data capture and processing capabilities.

About Anoto Group

Anoto Group is the company behind and world leading in the unique technology for digital pen and paper, which enables fast and reliable transmission of handwritten text into a digital format. Anoto operates through a global partner network that focuses on user-



friendly forms solutions for efficient capture, transmission and storage of data within different business segments, e.g. healthcare, bank and finance, transport and logistics and education. The Anoto Group has around 110 employees, offices in Lund (head office), Boston and Tokyo. The Anoto share is listed on NASDAQ OMX Nordic small cap list under the ticker ANOT. For more information: www.anoto.com