Clinical trials world wide aided by Digital Pen and Paper

“Cutting the time to approve a drug by one week can mean saving one million euro or more”

Massimo Raineri, Actelion Pharmaceuticals

Long, rough road to approval for medical trials
The road to approving a new drug is cumbersome. Clinical trials are extensive, detailed research studies which test the safety and efficacy of a drug. For those who could benefit by newly approved medication, the sooner the experimental drug is approved, the faster the ailing patient can be treated.

While these trials sound ominous and impersonal, they are still conducted one-on-one, with the doctor examining the patient.

The digital pen and paper solution has been used to collect Case Report Form (CRF) data in Phase I, II, III and IV international multi-centric clinical trials. Each patient has a CRF with forms to be filled out by the doctors during the trial.

Phase I: Drugs are given to healthy volunteers to see how the body adopts the drug, how long it stays in the body etc. The trial only lasts for a short time and is normally run in one single location.

Phase II: The drug is tested towards a placebo or existing drug on the market. The trial lasting for several months to several years are performed at the hospitals.

Phase III: Large trial involving several thousands of persons. The trial can last for years.

Phase IV: A post market surveillance after release of the drug to continue gathering epidemiology data and investigate unwanted side effects.

Revolutionized data capture the old fashioned way
Actelion Pharmaceuticals Italy conducts medical trials the world over. They use data capture tools – Anoto digital pen and paper technology, provided by Kayentis which record data for researchers in 12 trials throughout Western Europe, the United States, Australia and Israel. Data is handled with the help of a webbased system co-developed by Actelion and GM.

Benefits:
- Easily deployed. Very well received/accepted by trial study doctors. Ensures traceability of collected data.
- Reduces time a drug takes to get to market which may represent millions of euro in earned revenue.

FACTS

Customer: Actelion Pharmaceuticals Ltd.

Challenge: Speed up approval of new drugs. Make the cumbersome, costly and precise process more efficient. Improve quality and ensure high security of data capture.

Solution: Digital Pen and Paper solution developed by Actelion and GM Servizi, based on the Forms Automation System (FAS) Platform and printing services provided by Kayentis. The solution incorporating Anoto technology to capture, validate, integrate and process clinical research data using Case Report Forms (CRFs) printed with unique pattern to ensure complete traceability of collected data. 12 clinical trials conducted worldwide with about 500 pens in use.

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Servizi. There are more than 500 pens in use.

For each patient enrolled in a clinical trial a CRF is printed on paper with unique pattern. Research doctors use digital pens to record the data on the paper which allows a unique identification for each patient and each CRF field. This seemingly easy solution is very well received by doctors because it is already familiar and requires very little training and no change in the normal visit procedure.

Massimo Raineri, Head of Systems Development, Biometry at Actelion Pharmaceuticals explains: “Most doctors don’t like typing on a keyboard while examining a patient. They would have to look at a screen instead of into the eyes of the patient. That changes how both the doctor and patient behave and modifies the natural flow of data capture.” Mr. Raineri adds, “Doctors like this solution because it feels like using a normal pen.”

High quality data capture
Data captured with the digital pen and paper solution is uploaded daily, integrated and processed. However, because clinical trials have more stringent health authority requirements a redundant data transfer is required. When a visit is completed the CRFs are collected and all data is re-entered manually.

Normally the cost savings would be calculated by eliminating the need to transcribe collected data. In the world of clinical trials where quality cannot be compromised this additional loop is not significant.

Time is money
The digital pen and paper solution transpires into cost savings. Monitors, people paid by the pharmaceutical company, visit the investigational sites to review collected data. With the digital pen and paper solution, monitors can get a view of collected data prior to their visit. Mr. Raineri explains the significance, “These monitors are not coming in blind. They are not looking at the data for the first time. They can prior to their visit highlight possible reports that need to be examined and corrected.” The result is huge cost savings in less travel, better usage of

Partner profiles:
Kayentis:
Kayentis is an integrator and operator of digital writing professional solutions specialized in Healthcare and Life Science, Manufacturing and Services sectors. Kayentis range of services improves key company process performance. Data collected by physicians, nurses, but also technicians and clerks in demanding environments such as healthcare, manufacturing or services are subject to strict levels of security and traceability. The solutions are built on top of Forms Automation System, an industry standard platform, proven and answering the daily needs of thousands of pens users when it comes to print on demand, unique pattern and secured data exchanges.

www.kayentis.fr

GM Servizi:
GM Servizi: is a software house producing application systems based on the Web. They are mainly focused in building solutions for the Facility Management and Clinical Research markets and can supply customer with full systems ready for digital pen data collection and management or integration services of the Anoto technology in existing systems.

www.inkdata.eu

Customer profile:
Actelion Ltd. is a biopharmaceutical company with its corporate headquarters in Allschwil/ Basel, Switzerland. Actelion, founded in late 1997, is a leading player in innovative science related to the endothelium – the single layer of cells separating every blood vessel from the blood stream. Actelion’s over 1,200 employees focus on the discovery, development and marketing of innovative drugs for significant unmet medical needs. Actelion shares are traded on the SWX Swiss Exchange (ticker symbol: ATL.N).

www.actelion.com