

## ACTELION LTD AND DIGITAL PEN & PAPER SERVICES

### Actelion Pharmaceuticals

A leader in the market of pharmaceutical biotechnology, Actelion Ltd is a Swiss multinational present in 17 countries. Actelion Ltd is the pharmaceutical company that produces Tracleer®, the treatment for pulmonary hypertension, and Zavesca®, the only approved oral treatment against Gaucher's disease, a rare metabolism disorder. Founded in 1997, today Actelion Ltd counts almost a thousand employees.

### Clinical trials

Actelion Pharmaceuticals focuses on the discovery, development and commercialisation of innovative drugs and treatments. Its clinical pharmacologists test the new coming up compounds on humans to get an idea of their effectiveness and test if they are safe. The trials are done in many healthcare structures all around the world. When all the tests and assessments are done as set out in the protocol prepared for the investigator or physician, all the documentation of the results, like vital signs or adverse effects, are noted on the CRF. The CRF, when it is completed, becomes the end product of the clinical trial. Clinical trials are a crucial part of the research and development of new drugs, also for the licensing process.



### The CRFs

The Case Report Form (CRF) is central to trials, but processing the CRFs in the traditional way is not efficient and costly.

Previously the CRF were compiled using traditional pen with the disadvantage that the data was not available in real time to the various monitors, with a considerable loss, especially in terms of time.

### The technology

Actelion has brought new technology - Digital Pen&Paper - into its clinical trials, to simplify and to get faster the data from many CRFs used in registration studies.

Digital Pen&Paper technology consists of special pattern printed onto the paper and recognised by the digital pen, which is a standard ink pen with an integrated infrared camera. The data, written on the forms in the traditional way, is captured digitally and automatically uploaded to a server.

The solution allows full data traceability and ensures data integrity thanks to a unique ID that identifies each digital pen and each paper page.

GM Servizi developed with Actelion Ltd. the Digital Pen and Paper solution based on the FAS Platform originally provided by HP and now provided by Kayentis together with printing services. This solution makes use of Anoto technology to capture, validate, integrate and process clinical research data.

### **GM and C.A.D.P. Data Management System**

Digital Pen&Paper technology has been integrated by GM into the web based system of Data Management C.A.D.P. (developed by GM for Clinical Data Management and Data Processing).

GM developed an end-to-end solution including server-side application, system deployment, testing and documentation.

The functionality of the integrated system involved 2 distinct areas: the visualization/management of the data coming from the digital pen (which mostly uses the web platform developed by GM) and the printing of the CRF with a quality process.

Digital Pen&Paper usage has been “slowly” integrated step by step in Actelion Clinical Data Management system without any change in the investigators work: paper is still the primary clinical data source and the paper is collected at the end of the process.

### **Clinical trials conducted**

At the beginning of 2005 a pilot Clinical Trial phase I started in Germany using DigitalPen&Paper technology.

On April 2005 Actelion has conducted a phase II study using DigitalPen&Paper technology.



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There are currently 12 official clinical trials Phase II, III and IIIB/IV (observational and interventional, multicenters) running in Europe/US/Australia on this new technology. Their duration range is from few months up to 4 years with about 3000 planned patients. Some of these clinical trials have a complex CRF including patient's questionnaires and Operability Evaluation Forms.

### **Numbers**

More than 500 pens deployed.  
About 3.000 planned patients are foreseen in the activated studies.  
About 700 patients currently managed in the 12 active trials.

## Comparison with EDC and paper

Currently, there are three main input interfaces available for gathering clinical data: traditional pen and paper, EDC (Electronic Data Capture) and Digital Pen&Paper technology. In the comparison with the traditional paper, Digital Pen&Paper technology turns out winning particularly for Sponsors because data quality is better and Monitor's visits can be performed less frequently. For the Investigators there is no difference: the job to do is the same.

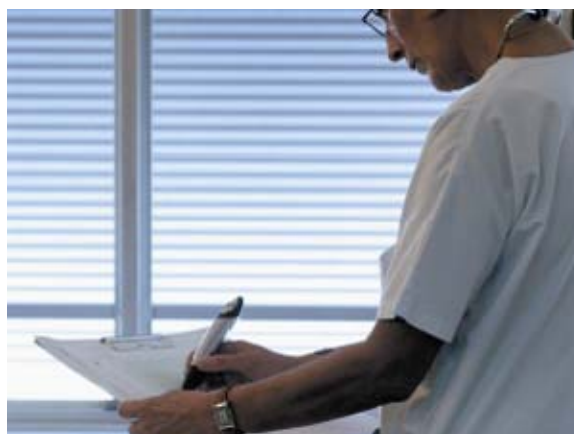
The comparison with EDC systems used (web based systems, PC/laptop, direct capture,...) demonstrates that Investigators consider Digital Pen&Paper technology less invasive than EDC systems: time required for visit is shorter, the training is simpler, patient interviews and consolidated working patterns are unaltered. Moreover, with EDC systems, Investigators "waste" their time typing on a keyboard!

## Benefits

Digital Pen&Paper technology is a well accepted tool to collect clinical data in a compliant and efficient way.

This is quicker and cheaper than the traditional methods, easy to use and requires a limited training.

Efficiency increased and time saved during development extend the market life of a drug that could add millions of dollars to sales.



## Evidences

"We believe that the use of Digital pen and Paper technology is a very good alternative to Electronic Data Capture (EDC) Keeping the ink and paper approach whilst enabling similar speed in data collection, avoids the burden of data entry at the investigational sites and simplifies the validation requirement and the training process."

*Maurizio Rainisio, vice president, head of Biometry, Actelion Pharmaceuticals Ltd*

For more information, please visit:  
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