

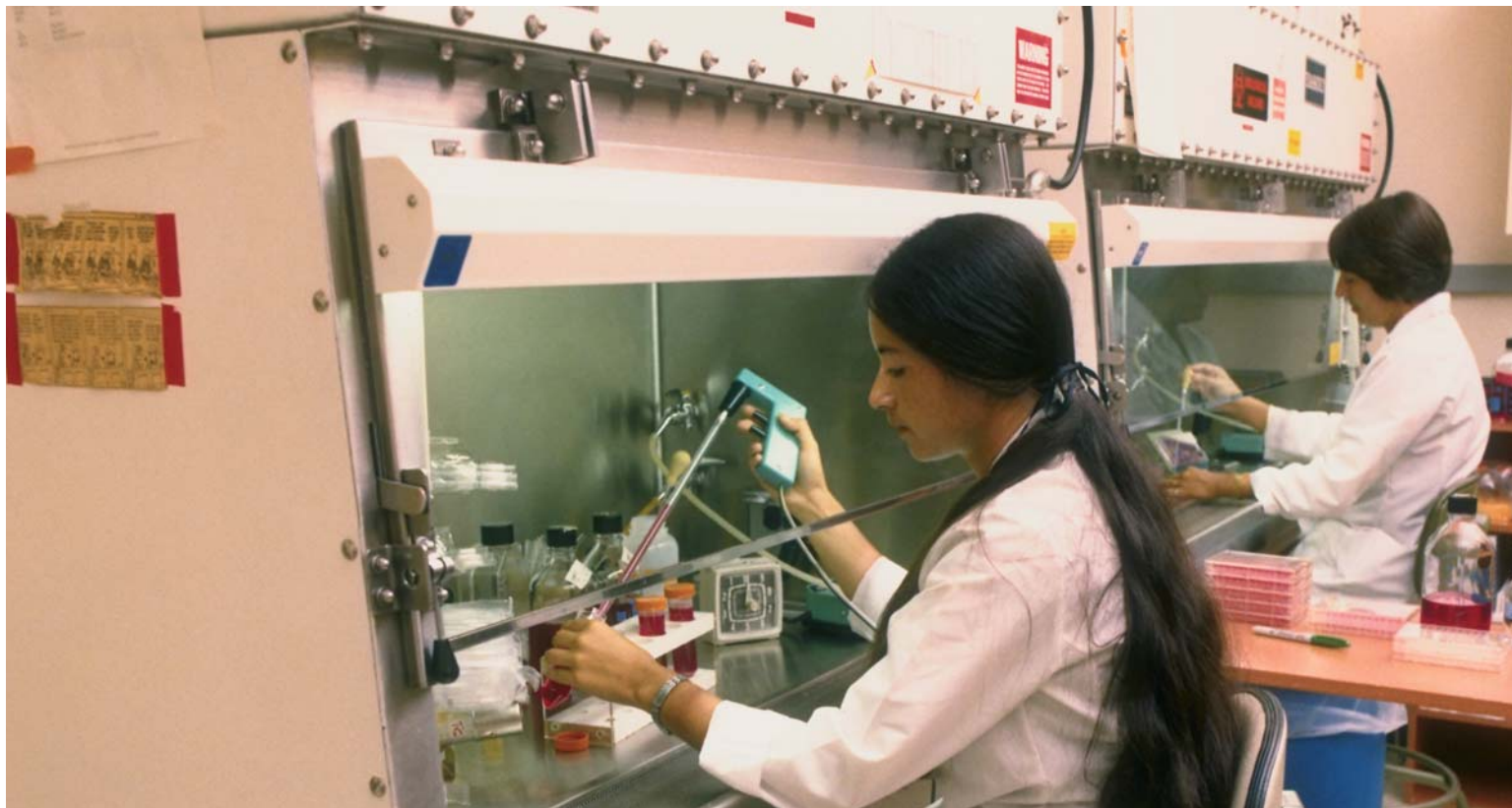
HP digital pen and paper could  
save millions for pharma leader



“Using HP Forms Automation System enables us to bring a drug to market earlier, which would be to the benefit of the patients. It saves both time and money and this is especially important in clinical development where every day you save can be worth a million dollars – and that’s not hypothetical.”

Paul van Giersbergen, senior clinical pharmacologist, Actelion Pharmaceuticals Ltd





Innovation is the watchword for Actelion Pharmaceuticals Ltd, a Swiss-based leader in the global biopharmaceutical market.

Present in 17 countries, Actelion Pharmaceuticals focuses on the discovery, development and commercialisation of innovative treatments. Its lead product is Tracleer for the treatment of pulmonary arterial hypertension, a chronic life-threatening disorder that affects the lungs and heart. Its secondary product is Zavesca, which is the only approved oral treatment for Type 1 Gaucher's disease, a rare debilitating metabolic disorder.

Clinical trials are a crucial part of the research and development of new drugs, not only to ensure that they are safe and effective for patients, but also for the licensing process.

#### **New technology**

Showing the same innovation that applies to its research and development, Actelion Pharmaceuticals has brought new technology into its clinical trials by employing the HP Forms Automation System (FAS) otherwise known as Digital Pen and Paper, to create Case Report Forms (CRF) that are used to document findings.

Developed to speed up the completion of CRFs, FAS consists of special fields printed onto the paper and recognised by the HP Digital Pen, which is a standard ink pen combined with an integrated infrared camera. As

users write on the forms in the traditional way, data is captured digitally by the pen and when it is returned to its cradle, the data is automatically uploaded to a server. As each CRF is uniquely identified and every HP Digital Pen has a unique ID, the solution allows full data traceability and ensures data integrity.

GM Servizi is a key system integrator and web applications developer for Actelion. "We have focused our efforts on integrating HP FAS within the existing Actelion Pharmaceuticals web data management system. Thanks to HP's complete software development kit and CRF printing expertise, we've been able to work with Actelion Pharmaceuticals in developing an end-to-end solution including server-side application, system deployment, testing and documentation," said Mimmo Garibbo, general manager of GM Servizi.

#### **Specialist trials**

As a drug development company, Actelion Pharmaceuticals uses chemistry and biology to come up with new compounds, and it is the task of its clinical pharmacologists to test these compounds on humans to see what the pharmacokinetics look like, to test if they are safe and to get an idea of their effectiveness.

"The trials are usually done in specialist clinics that only carry out clinical trials on healthy volunteers and special patient populations. When all the tests and assessments are done as set out in the protocol prepared for the

investigator or physician, 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," said Paul van Giersbergen, senior clinical pharmacologist with Actelion Pharmaceuticals.

Previously, CRFs were completed using normal pen and paper. This method had the disadvantage that real time data was not visible to the monitors whose job it was to oversee the trials. To see what was happening with the trials, they had to book an appointment and travel to the clinic which was time wasting and costly, and before they arrived, they had no idea of the current situation.

#### **Time savings**

"Moving to the HP Forms Automation System means we will have access to data in real-time, with data being immediately available when staff return the special pen back to its cradle. This would save time and give the monitors a good idea of the situation or any problems before they visit the clinics, which is another big advantage," added van Giersbergen.

#### **Long term advantages**

Actelion Pharmaceuticals has already used the HP Digital Pen and Paper technology for two Phase I trials at clinics in Germany and these have been so successful that they intend to conduct more Phase III trials in Europe, US and Australia within the year. A Phase III patient trial in Europe and US using the FAS technology has already been started.

"Using HP Forms Automation System enables us to bring a

drug to market earlier, which would be to the benefit of the patients," said van Giersbergen. "It saves both time and money and this is especially important in clinical development where every day you save can be worth a million dollars – and that's not hypothetical. If you have a drug that sells for \$365 million a year, it will sooner or later lose its patent and usually at a time when sales are at their highest, so if new technology like this can save you weeks or months in development time, you have a longer time on the market before the patent runs out and that makes a big difference."

The HP Digital Pen and Paper technology is also a big success with the people who have actually used it day to day. Katja Nedoschinsky, a study nurse at Tropon GmbH who carries out trials for Actelion Pharmaceuticals said: "The advantages of HP Forms Automation System are fast data transfer and the elimination of error. It is very easy to use with little training and it saved me considerable time when transferring data from the CRFs. It is a great advance over the normal pen and paper method."

Maurizio Rainisio, vice president, head of Biometry at Actelion Pharmaceuticals concludes: "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 requirements and the training process."



## At a glance

- **Industry sector:** Biopharmaceutical
- **Name:** Actelion Pharmaceuticals Ltd
- **Headquarters:** Allschwil, Switzerland
- **Founded:** 1997
- **Telephone:** +41 61 565 6545
- **Number of employees:** 950
- **URL:** [www.actelion.com](http://www.actelion.com)

## Partner a glance

- **Company:** GM Servizi
- **Headquarters:** Imperia, Italy
- **Telephone:** +39 0183 660023
- **URL:** [www.gmserv.com](http://www.gmserv.com)
- **Business:** Technical services, solutions and consulting for Internet technologies

## Challenge

- Actelion Pharmaceuticals Ltd is a leader in the biopharmaceutical market and clinical trials are crucial in the development of its drugs.
- The Case Report Form (CRF) is central to these trials, but processing the CRFs in the traditional way is not efficient and is costly.
- It means that the monitors who oversee trials cannot get a real-time overview of what is happening without travelling to the clinics where the trials take place.

## Solution

- Actelion Pharmaceuticals has conducted two Phase I clinical trials using HP Forms Automation System (HP FAS) based on Digital Pen and Paper technology to fill in CRFs and has started a Phase III clinical trial in US and Europe.
- Developed to speed up the completion of routine forms, HP FAS consists of an end-to-end solution including CRF printing, HP Digital Pen, and HP Workflow Connect - server software allowing a seamless integration into Actelion's web data management application.
- As users write on the CRFs in the traditional way, data is captured digitally by the pen and when it is returned to its PC cradle, the data is automatically uploaded to Actelion's application.

## Results

- The two clinical trials, carried out in small specialist clinics, were a great success and full-blown patient trials are now to be conducted in hospitals.
- Using FAS is quicker and cheaper than the traditional method and it also provides Actelion's monitors with real-time information on results or problems before they visit the trial sites.
- The system is very convenient and easy to use and requires limited training.
- Increasing efficiency and saving time during development extends the market life of a drug that could subsequently add millions of dollars to sales.

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