



kayentis

The best of both worlds

SUCCESS STORY

LATE PHASE

So intuitive to collect data
So effective to share information

KAYENTIS PLATFORM ALLOWS TO ACTELION SAVING MILLIONS

ACTELION PHARMACEUTICALS Ltd



Actelion Pharmaceuticals Ltd is a biopharmaceutical laboratory with headquarters based in Allschwil/Basel, Switzerland. Founded in 1997, it is a major player in scientific innovation regarding the endothelium. With

1,200 employees, Actelion focuses on the research, development and marketing of innovative drugs for significant medical needs that are not met.

Background: For Actelion, clinical trials are a crucial part of drug development. The Case Report Form (CRF) lies at the core of these trials, but processing it using conventional methods is inefficient and very costly. The people who supervise the trials cannot have a real-time vision of what's happening unless they actually travel to the medical center where the trials are held.

Solution: Actelion has conducted many clinical trials worldwide with Forms Automation System (FAS), which is based on the Digital Pen & Paper Technology, and has begun a phase II clinical trial in the USA and in Europe. Developed to accelerate the filling in of routine forms, the Kayentis system represents an end-to-end solution including CRF printing, digital pen and the Clin'Form® application, which integrates simply in the Actelion data management system. As users complete the form, the information is captured in the pen. When the pen is returned to its inkwell, the data is automatically downloaded to the Actelion application.

KAYENTIS is the leading vendor and operator of solutions that transmit handwritten text from paper to digital media for the healthcare industry.

Based on KAYENTIS' Digital Pen and Paper platform, these solutions bring together the best the physical and digital worlds have to offer: the easiest collection method (paper and pen) offering the highest data quality combined with all the advantages of electronic management (real-time access to data, accurate timestamps, audit trail features, alerts, distribution of relevant information to the right persons).

KAYENTIS' solutions are used for over **50,000 patients in 50 countries**.

KAYENTIS is a member of the Medicen, Lyon Biopôle, Pennsylvania BIO and BIO New Jersey clusters. Kayentis is an Anoto Platinum Partner, an Oracle Partner and an HP Solution Business Partner.

For more information, please visit: www.kayentis.com



Kayentis is one of **ANOTO's** very first international partners and has earned the distinction of being an Anoto Platinum Partner.

BENEFITS

- Faster and less expensive technology than conventional collection methods
- Immediate transmission of results, enabling remote data reception and checking
- Intuitive use that does not require any special training
- The increased efficiency and time saved during development extends the life of the drug

WHAT THE EXPERTS ARE SAYING

Paul van Giersbergen

Senior Clinical Pharmacologist
Actelion Pharmaceuticals Ltd

// Forms Automation System allows us to get a drug to market faster, which is a patient benefit. The system saves time and money, which is particularly important in clinical development, where a gain of one day can mean a million dollars saved – and this is not just hypothetical //

Established in 17 countries, Actelion Pharmaceuticals focuses on the discovery, development and marketing of innovative treatments. Its two flagship products are Tracleer (pulmonary hypertension) and Zavesca (the only approved oral treatment for Gaucher's type 1 disease, a rare and debilitating metabolic disorder).

Clinical pharmacologists are responsible for testing these treatments on humans in order to observe their pharmacokinetics aspects, to check that the components are safe and to gain an idea of their effectiveness. Clinical tests represent a crucial part of the R&D on new drugs to ensure their safety, effectiveness and the marketing authorization process.

In the past, CRFs (Case Report Form) were completed using conventional paper and pen. The data could not be viewed by the person in charge of supervising the trials. To see what was happening during these tests, they had to go to the medical center, which was a waste of time and money.

An innovative technology

To meet these constraints, Actelion introduced a new technology in its clinical trials by using the Kayentis Forms Automation System (FAS) which is based on the concept of creating electronic CRF forms that are used to collect patient data.

Developed to accelerate CRF treatment, FAS consists of a special pattern printed on standard paper and recognized by the digital pen. The digital pen is a conventional pen combined with an infrared camera. As users complete the data according to standard practice, the data is recorded digitally by the pen. When the pen is returned to its inkwell, the data is automatically

downloaded to a server. **Each CRF contains a unique reference and each digital pen has its own identifier. This combination allows the origin of the data to be traced and guarantees its integrity.**

Massimo Raineri, Director of Biometric Systems Development at Actelion, explains: **"Most physicians don't like to enter data on a keyboard while they're examining a patient. It changes the physician's and the patient's behavior and introduces a bias when entering the data."**

"With Kayentis's FAS solution, we have access to the data in real time, as soon as the personnel returns the digital pen to its inkwell. This implies savings in time and gives the persons in charge of supervision a good idea of the situation and of any problems, before they go to the medical center, which represents another major advantage," adds Paul van Giersbergen.

Long-term advantages

"Using FAS by Kayentis allows us to market a drug faster, which is a patient benefit. It saves time and money, which is particularly important in clinical development, where a gain of one day can mean a million dollars saved, and this is not just. If the sale of a drug reaches \$365 million per year, at some time or another, you will lose its patent, and it's usually when sales peak. So this kind of technology can save you weeks or months in development. Your stay on the market before the patent expires is longer, and that changes everything," states Paul van Giersbergen.

DPP technology has also encountered strong success with everyday users. Katja Nedoschinsky, a nurse in training at Tropon GmbH who has conducted trials for Actelion, says: **"The advantages of FAS are fast data transfer and no more errors. It is very easy to use with just brief training and it allowed me to save a tremendous amount of time in the CRF data transfer part. It represents a real breakthrough compared to the use of conventional pen and paper."**

SUCCESS STORY

LATE PHASE

Maurizio Rainisio, Vice-President and Director of Biometrics at Actelion, concludes: **"We believe that the DPP technology is an excellent alternative to electronic data capture (EDC). By keeping the ink and paper approach, the time to enter the data is similar but the problems tied to data entry on research sites are diminished, and the approval requirements and training process are simplified."**

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