



Unique System Tool Boosts Efficiency of Clinical Trial Processes and Product Launches

A Swedish team of specialists within the American software company SAS Institute has launched a web-based solution that increases the efficiency of clinical trial processes. With no more than an ordinary mobile phone link, clinical data can be fed into the system and validated, anywhere at anytime. Several of the world's leading pharmaceutical and medical technology companies, including Gambro, Pfizer and Wyeth-Lederle, have already implemented the solution. The unique accessibility and simplicity of the system has made it possible for companies to identify the wide range within product launches and marketing.

With 25 years' experience, SAS Institute is today is the leader in business intelligence and analytics. Our software answers strategic business questions no one else can – enabling you to control costs, drive revenue, achieve capital efficiency and lead with confidence. With more than 40,000 customer sites worldwide, including 96 of the top 100 of the Fortune Global 500, SAS Institute is the world's largest privately held software company.

SAS Institute is specialised in software solutions that can handle, compile, analyse and intuitively present very large quantities of data. That is why it has for over 20 years been a valuable partner for businesses in the pharmaceutical and medical technology sectors. SAS Institute has acquired unique expertise and set up a global Life Science team. Perhaps the best example of SAS Institute's competence is the U.S. Food and Drug Administration's use of SAS software, which is also mentioned in FDA regulations on the handling of electronic files.

SAS Institute's Swedish team was able to identify the need for a simple and easily accessible solution for managing clinical trials by working close to pharmaceutical and biotechnology companies. As a result, the team developed PheedIt in collaboration with the Swedish IT consulting company Know IT.

"We wanted to create a solution which was easy to implement, simple to set up new studies, and also to analyse and report the trials. It could effortlessly be managed by the clinical trial coordinator. PheedIt also makes it possible to follow FDA 21 Part 11 in the entire clinical trial process. In this we have succeeded," explains Ann-Sofie Bergström

in SAS Institute's Swedish Life Science team.

"I would like to stress that its ease of use is quite unique," adds her colleague Carl Olow Magnusson. "The only thing you need to retrieve reports is an Internet connection. We have even tested to enter and retrieve reports via an ordinary GPRS mobile phone, with good results."

Complete Web-Based Solution

PheedIt is a complete solution that supports the whole process chain from data feeding through validation, cleaning, analysis and presentation. Based on a single product, it can easily be combined with other systems and data sources. Its purpose is to make it easy for clinical trial coordinators to administer the system and for doctors and research nurses to manage their studies at the clinic. The solution is also used for sharing information on current trials, amendments, meetings, number of recruited patients, etc.

"An important principle in the development of PheedIt was, that it should be quick to implement. It only takes three to five days to implement the whole system, including installation, validation

and training. Considering that many other solutions can take one or two years to implement, we can be proud of our solution. Pheedlt's short implementation period is very cost effective, then the clinical trial users are self-sufficient. An existing study can be copied and used as a basis for a new one in a question of minutes," says Ann-Sofie Bergström.

Improvements for Everyone

A guiding principle for the system was to make the work easier and more efficient not just for clinical trial coordinators but also for any participating user such as investigators. By using a web and data transfer technique that allows maximum accessibility has made the data feed process user-friendly and validation quick and simple, helping users to avoid unnecessary trouble and repetition. This means significant reductions in time and costs. When users at various clinics log into Pheedlt, they reach a portal whose news window gives them the latest update and instructions from trial coordinators. They can use statistics from their research studies to compare things such as patient recruitment rates, deviations and schedules between clinics. Users with the access rights can also retrieve reports in the form of data lists or graphs.

Satisfied Customers

Medical technology company Gambro uses Pheedlt for its clinical studies. "We are happy with the system, it satisfies our needs," says Gambro's clinical trial director.

Another world-leading company uses Pheedlt for all its clinical trials. Implementation was very swift; installa-

tion was done at the end of January, staff training carried out in February, and the first test study input made in early March. The system is now used for trials carried out in Europe and the US, with reports sent via the intranet to a central trial coordinator.

He is very pleased with Pheedlt: "We were looking for a user-friendly system that was FDA 21 Part 11 compatible, and we found it in SAS Institute's Pheedlt. In our unit it has contributed significant improvements to data management. The quality of our data has increased and reporting times have been reduced by 20-30 per cent. This is mainly thanks to the system's user-friendliness. We can also design new studies using our own parameters, and it is easy to tailor the reporting of results. Our researchers out in the field can use the web to receive flash reports on the study's progress."

"Our cooperation with SAS's Pheedlt team has been constructive, bringing us added benefits. The team listened carefully to our wishes and needs and got back to us quickly on questions we found important. They also know our sector well. The use of Pheedlt is now compulsory in our division, and our marketing division has increasingly begun testing its application – for instance to so-called Phase 4 studies," he adds.

A data manager from another company says, "Pheedlt is a brilliant solution. It is a robust product and easy to use. Its user interface is exceptionally well thought-through. The fact that it is designed for use in clinical trials was a quality guarantee for us, as we strive to make our non-clinical studies as

quality-assured and well documented as our clinical ones. It was also important that the product would allow for our growth, which meant that the supplier of the solution had to be a stable company with a high level of competence and expertise within our sector. SAS Institute fulfils these criteria."

Unique Platform for Wyeth

The Swedish subsidiary of Wyeth Lederle has also seen the potential and value of SAS Institute's Pheedlt solution. IT Director Allan Christensen has planned to take its use one step further. "We acquired Pheedlt to boost the efficiency of our clinical trials. The main goal was – and still is – to increase the quality and speed of the trials and to support the doctors' involvement in it. With Pheedlt, doctors can follow up on studies, as well as retrieve information and present it clearly. This increases their commitment to and faith in Wyeth," he says.

"This is something we can make use of in all Wyeth divisions. Pheedlt's portal is a direct platform for a select, dedicated team of people who make use of the information on it and send information back to it. This would be an excellent way for our marketing department to communicate with the right target group before seminars and conferences, or for providing doctors with product and research data. I believe that this will increase clinical workers' interest in Pheedlt. The product makes it possible for us to create added value for doctors and other health care staff," concludes Allan Christensen.



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