

CLINICAL DATA WAREHOUSE FOR LARGE PHARMACEUTICAL COMPANY

NNIT helps pharmaceutical company increase the value of its clinical data

For a large research-based pharmaceutical company, getting products to market quickly is a critical requirement. But this pharmaceutical company had a problem: it didn't have enough statisticians to quickly process and analyse all the data it had collected from clinical trials. As a result, it was struggling to re-use its historical data in cross-data analyses, and was slow to respond to enquiries from regulatory authorities.

The answer was a Clinical Data Warehouse from NNIT that standardised data from all the company's clinical trials. The result was better use of data, faster responses to regulatory authority enquiries, and, ultimately, a shorter time to market.

THE CHALLENGE

For many companies, IT infrastructure develops over time – and this can often lead to a complex mix of systems and programs. At some point, standardising IT systems becomes more than a 'nice to have'; it becomes essential for the future success of the business. This was the case for this research-based pharmaceutical company.

Over the years, the company had conducted hundreds of clinical trials – but the data had been collected in a number of different ways. This made gathering and analysing the data extremely difficult – and the process was proving too time-consuming for the company's large team of statisticians. As a result, the company was slow to respond to regulatory enquiries, and was failing to make good use of the data it had collected in older trials.

The company called in NNIT, and the NNIT team developed a solution that standardised the data – even from old trials – making it quicker to gather and easier to work with.

THE SOLUTION

Much clinical data is collected through questionnaires. But for this customer, the questions and data fields varied from questionnaire to questionnaire, and this made working with the data difficult.

Anders Høyer Svendsen, an NNIT Component Architect on the project, explains, "One bizarre but simple example was the gender fields. Some questionnaires may use three options: male/female/other; while other questionnaires could use just male/female or even male/female/both. Statistical analysis programs can't deal with the differences, so when a statistician wanted to use the data, they had to go through a time-consuming alignment process."

NNIT's solution was a Clinical Data Warehouse (CDW) – a complete solution for gathering, transforming and exporting clinical trial data. The solution itself is split into two sections. The web application, CDWO, gathers the data. It also includes a mapping tool that ensures all the information from each trial is standardised. This is done manually, but the CDWO speeds up the process significantly by using pre-programmed mapping patterns to recognise and automatically import all like data. The CDWO also allows users to insert meta-data for each trial, such as trial cut-off dates and the number of participants.

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The second part of the CDW is the Data Processing engine. This extracts the data from the CDWO, transforms it and loads it into a Clinical Data Repository. From here the data is instantly available to users, and can be quickly exported to a statistical computing environment – in this case SAS Drug Development.

THE RESULT

With the CDW in place, the customer's team of statisticians now has faster access to standardised data. This means they can do more work in less time. The system has already proven to reduce the amount of time it takes for the company to respond to enquires from regulatory authorities. And all this shortens the time it takes to get regulatory approval for a new product – and reduces time to market.

But equally importantly, the standardised system means data from older clinical trials can be re-used and compared to new data in cross-trial analyses – vastly increasing the value of the company's data. The next step is for the company to import the data from all its previous trials. Once this is done, it will have fast access to all the trial data it has ever produced – a significant competitive advantage for any research-based company.

ABOUT THE CUSTOMER

A large research-based pharmaceutical company, the customer employs more than 25,000 people in more than 80 countries. The company develops, produces and markets medicines in a number of therapeutic areas.

ABOUT THE CLINICAL DATA WAREHOUSE

- A system for standardising data
- Makes it possible for everybody to access the same data in near-real time
- Compatible with standard technologies such as Oracle LSH, SAS DD and WABAN
- Helps ensure faster statistical analysis and quicker response time to regulatory authorities

FURTHER INFORMATION

Please contact us at nnitcontact@nnit.com to learn more about the case or our Clinical Data Warehouse.

ABOUT NNIT

NNIT is an international IT service provider offering IT consulting and the development, implementation and outsourcing of IT services for regulated industries. We create value for our clients by treating their IT as if it were our own. We use IT to support our clients' daily operations and help them achieve their business goals. Owned by Novo Nordisk, NNIT employs nearly 1,300 people. In 2008, our turnover exceeded €185 million.