

# CLINICAL DATA WAREHOUSE FOR MAJOR PHARMACEUTICAL COMPANY

## NNIT consolidates data for major pharmaceutical company

As a leading manufacturer of pharmaceuticals, our client needed an efficient system for exchanging and storing clinical data. Our client also needed to standardise data in order to be exchanged with external partners in a structured, meaningful way. Standardised data would also speed up the approval process with the FDA, enabling our client to get products to market faster.

A clinical data warehouse from NNIT was the answer. Based on Oracle's Life Sciences Data Hub (LSH), NNIT's clinical data warehouse provided the client with the right tools and infrastructure to perform cross-study analyses, be in compliance with regulatory authorities – and grow its business.

### THE CHALLENGE

When the client came to NNIT, data from each clinical trial was stored in separate databases. The process began with a physician entering data electronically or manually. Data was then transferred to a clinical database, and checked before moving on to the results process. As a consequence, data from various trials was scattered across the organisation, and it didn't necessarily meet international standards. In general the system wasn't sufficient and posed several problems for our client.

As a growing business, the client didn't have the resources to run all the data trials it was planning. Furthermore reusing existing data and accessing the information inside the data was not possible. This made it difficult to exchange data with partners, and it made product acquisitions and selling off of the portfolio challenging.

The client needed a standardised storage facility for data and the information in the warehouse needed to match the standards set by the FDA. In order to keep one step ahead it was crucial to anticipate what the FDA would look for and to be able to review the data just like the FDA would.

### THE SOLUTION

According to Senior NNIT Project Manager Philip Puls NNIT was brought in early in the process because the client knew NNIT had the right experience with clinical data warehouses. Says Philip Puls, "They invited us because we understood their specific requirements and needs – and we had the ability to implement the right solution in collaboration with them. They couldn't find this knowledge anywhere else."

NNIT conducted an initial analysis and helped the client structure the selection process from software and vendors. Then, working closely with the client, NNIT produced a clinical data warehouse that was more than just a repository for data; it was also a system for harmonising, standardising and making efficient use of all trial data. Based on Oracle's LSH database and a customised component developed by NNIT for the pharmaceutical industry, NNIT's clinical data warehouse solution



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ensured the client complied with industry standards.

The LSH-based solution from NNIT offers accurate and timely information, providing the organisation with an integrated environment for clinical data and the ability to make better decisions. NNIT's Business Integration Leader Andreas Birch is pleased with the solution: "All data is automatically standardised to international standards. This is a great benefit. It means that the data is now consolidated and available for cross-study analysis – and the client can quickly answer queries from regulatory bodies."

## THE RESULT

NNIT's clinical data warehouse was delivered on time and on budget. Now the client has a single repository for all data from all clinical trials. The data is guaranteed to meet CDISC (Clinical Data Interchange Standards Consortium) and CDASH (Clinical Data Acquisition Standards Harmonization) international standards.

And by ensuring data is structured in a way that meets FDA standards, the client can move faster through the approval process, reducing the time and the costs involved in the approval. Also, because the data processes in the warehouse are streamlined, the client experiences long-term efficiency gains.

The implementation project is now complete, but a few NNIT people are still involved on a day-to-day basis in support functions. And the successful partnership is continuing. NNIT and the client have a series of new projects in the pipeline, and the client may wish to expand the functionality of the clinical data warehouse in the future – if so, NNIT will be there to help.

## ABOUT THE CLIENT

The client is a privately owned global pharmaceutical company with a differentiated portfolio of branded medicines and an extensive range of OTC products. The company has over 12,000 employees across the globe and its products are available in more than 100 countries. The company generated total sales of €3.4 billion in 2008.

## ABOUT CLINICAL DATA WAREHOUSE

- Based on Oracle's Life Science Data Hub
- FDA-based standards model allows the client to review data the same way the FDA would
- Data can be reused and exchanged with partners
- Data storage facility with built-in quality control measures

## FURTHER INFORMATION

Please contact us at [nnitcontact@nnit.com](mailto:nnitcontact@nnit.com) to learn more about the case or our clinical data warehouse services.

## 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.