

Bayer improves collection of clinical trial data with help from IBM

Overview

■ Challenge

With the pharmaceutical industry under increasing pressure to raise productivity and cut drug development costs, Bayer realised that innovation was key to maintaining its market competitiveness. To bring good new drugs to market more quickly, it needed to reduce the time spent gathering and analysing the data it collected during clinical testing.

■ Why become an On Demand Business?

Bayer realised that an innovative, global approach was required to enable it to make faster decisions about which drugs to concentrate on, and to bring those drugs to market more quickly. This in turn would assist Bayer in fulfilling its mission of helping patients lead healthier lives.

■ Solution

Working with IBM Business Consulting Services, Bayer selected and implemented a new global Electronic Data Capture (EDC) system for collecting and managing trial data electronically, replacing a localised, in-house system. With help from IBM, Bayer was able to identify the impact on processes and to adapt them to realise the full benefits of the new



global approach. IBM Information Technology Services assisted Bayer in establishing a global 24/5 service desk to support the trial doctors and Bayer personnel using system.

■ Key Benefits

- Reduction in time taken to gather clinical data – from weeks to near real-time
- Faster, more efficient processing of information enabling Bayer to develop drugs more quickly, reducing time to market.
- Enhanced global co-operation, resulting in increased efficiencies and cost savings.

» On Demand Business defined

An enterprise whose business processes – integrated end-to-end across the company and with key partners, suppliers and customers – can respond with speed to any customer demand, market opportunity or external threat.

When German chemist Felix Hoffman discovered aspirin in 1899, his employer, the dye-maker Bayer, became the world's first pharmaceutical firm. Today, Bayer Healthcare employs over 35,000 people and generates annual sales of about €8.5 billion. Its portfolio of products includes household names like Alka-Seltzer, Canesten and Berocca. It is also a pioneer in the development of proteins manufactured using gene technology, and has promising cancer and cardiovascular drugs in its pipeline.

Paper chase

The pharmaceutical industry is finding it increasingly difficult to develop good new products. Many of the drugs being researched are very complex; the number of candidates that fall by the wayside is rising; and clinical testing costs an enormous amount of money.

On Demand Business Benefits

- Reduction in time taken to gather clinical data – from weeks to near real-time
- Faster, more efficient processing of information enabling Bayer to develop drugs more quickly, reducing time to market.
- Faster access to trial data enables more informed decision-making, allowing Bayer to focus only on most promising drugs
- Cost reduction thanks to lower data collection and system maintenance costs.
- Clear, global, cross-functional processes enable enhanced co-operation and more informed decision-making.
- Bayer better positioned to focus its resources on developing the therapies and cures of the future.

One of the biggest obstacles in resolving such problems is the fact that most pharmaceutical companies still use paper-based processes for recording patient data during trials. This increases the number of errors that are made at the point of data entry and often results in a three- or four-month delay before the information can be accessed. Electronic data capture (EDC) – the capture and management of trial data electronically – greatly improves the quality of the information that is initially collected and ensures that it is available on a near real-time basis.

A state-of-the-art global system

The biopharmaceutical sector is very diverse, which makes it extremely difficult to identify the EDC product that will best meet an individual company's requirements. Moreover, most EDC software vendors are quite small and unused to working on the same scale as big pharmaceutical companies.

Bayer was already familiar with using EDC, but the home-grown system it had employed for some years was no longer sufficient for its needs, so it started searching for a commercial system that it could use worldwide. Its previous experience was a big advantage. Nevertheless, it realized that selecting and implementing a new EDC system that supported new global processes and working practices wouldn't be easy.

Winnowing out the winner

Recognising these challenges, Bayer decided that it needed help sifting through the many EDC systems on the market, so it appointed IBM. "We knew we could rely on IBM to give us honest, independent advice," says Bill Baker, Bayer's Deputy Director of Data Management. "We also wanted assistance with the technology transfer."

Together with IBM Business Consulting Services, Bayer drew up a list of its key requirements and started exploring the alternatives. Most of the 70-odd EDC systems the project team evaluated were unsuitable but, after extensive research, the team chose Medidata's Rave™. "It wasn't a perfect fit," explains Baker. "However, it had the potential to evolve and no commercial system will work perfectly for every company."

A global approach required global, cross-functional process changes, and the IBM team worked closely with Bayer and Medidata Solutions Worldwide to identify the processes Bayer needed to alter to harness the full benefits of the new system. IBM advised on both process and role changes for the staff involved in managing the collection of trial data before running repeat simulations to test these new ways of working.

"We knew we could rely on IBM to give us honest, independent advice."

Bill Baker, Deputy Director of Data Management.

The IBM consulting team provided additional support in the form of change management, the development of an appropriate IT architecture, integration of Bayer's existing trial management systems and training.

Rave™ is now live, and being used to manage all the new trials Bayer conducts in-house. "Working with experienced IBM consultants who were familiar with the technology, impact on internal processes and overall benefits was a huge factor in achieving a painless rollout," says Johann Proeve, Global Head of Data Acquisition and Management.

Up and running

The move, which took just over 14 months, has freed Bayer to concentrate on its core activities and reduced its maintenance costs. Importantly, it has equipped the company with a solution that physicians find very user-friendly.

"The new system has helped us globalise our overall data management processes – and clear, global, cross-functional processes enable all the parties involved in an electronic trial to co-operate smoothly," Proeve explains.

However, IBM's involvement does not end there. Bayer has appointed the company to provide EDC help-desk services for all trials conducted with Rave™ over the next three years. It is also exploring the opportunities for working with IBM on a broader "e-clinical" agenda that includes integrating information from other sources, such as drug safety reports and central laboratory data, with the data recorded in its EDC system. "A technically strong partner can help us move to the next stage – downloading clinical data from hospital and clinical systems without having to input the data again," says Proeve.

Bayer now has a head start over the many pharmaceutical companies that still rely on manual, paper-based techniques, with faster access to cleaner trial data. The company can focus its resources on the most promising drug candidates and maximise returns on its substantial investment in research and development, enabling it to develop the therapies and cures of the future.

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Johann Proeve, Global Head of Data Acquisition and Management.



Key Components

Services

- IBM Business Consulting Services
- IBM Information Technology Services

Why it matters

With vast sums of money devoted to research, pharmaceutical companies are under enormous pressure to increase productivity and reduce costs. To focus only on the most promising drugs and to get those drugs to market more quickly, Bayer realised that innovation was key. Already a leader in the use of Electronic Data Capture (EDC), Bayer decided to extend its use of EDC and to implement it on a worldwide basis. By advising Bayer on the selection of a new EDC system and the implementation of global, cross-functional processes, IBM was able to support Bayer in its innovative approach.



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