

LEO Pharma Adopts Electronic Data Capture to Streamline Clinical Trials and Regulatory Review



LEO Pharma A/S
Ballerup, Denmark
www.leopharma.com

Industry:

Life Sciences

Annual Revenue:

US\$883 million

Employees:

3,000

Oracle Products & Services:

Oracle Remote Data Capture
Onsite
Oracle Clinical
Oracle Thesaurus Management
System

Key Benefits:

- Reduced clinical development time
- Reduced resource requirements, enabling more clinical trials
- Improved safety monitoring
- Full integration with Oracle Clinical and Thesaurus Management System
- Decrease time to prepare e-submission-ready case record forms

“Oracle Remote Data Capture Onsite 4.5.3 provides us with powerful new functionality to help address two critical issues confronting the pharmaceutical manufacturing industry today—increasing the productivity and efficiency of investigation sites and accelerating the regulatory approval submission process.”
— Alastair Clewlow, Head of Clinical Data and Document Management, LEO Pharma.

Founded 100 years ago, Denmark-based LEO Pharma has thrived by staying focused on research. The privately owned pharmaceutical company is a world leader in dermatology, specializing in drugs for treating skin diseases such as psoriasis and eczema. It also makes a line of drugs for the treatment of critical conditions such as thromboembolic disorders.

LEO Pharma’s commitment to research has rewarded the company with years of earnings growth and an expanding customer base. Today, LEO Pharma is represented in more than 90 countries and employs around 3,000 people worldwide. As it prepares for the business challenges ahead—including a tougher competitive and regulatory environment—LEO Pharma has shown a capacity for innovation and a readiness to adapt.

For example, LEO Pharma has been among the first to embrace efficient new methods for managing clinical trials, an essential part of developing new drugs and therapies. In a recent initiative, the company adopted an all-electronic approach to collecting clinical data, implementing electronic data capture (EDC) technology from Oracle to shorten trial timelines and ensure faster approval by regulatory agencies.

The potential benefits of faster clinical trials are well known in the industry. One frequently cited benchmark estimates that every day gained in accelerating product registration could be worth US\$2-3 million in additional sales revenue. Companies also point to a host of related benefits from EDC technology, such as better safety checks, lower costs and higher quality data.

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“The business imperative is to get to market as quickly as possible without compromising the integrity of trials or the safety of patients,” says Alastair Clewlow, head of corporate clinical data and document management for LEO Pharma. Clinical trials in particular have emerged as one of the more expensive and time-consuming components of overall drug development programs, sparking investments in ways to automate and accelerate the process.

Faster Clinical Trials

With a number of drugs in the pipeline, LEO Pharma keeps its clinical development teams busy year-round. The company typically has 10 to 15 trials running concurrently at investigation sites spanning Western Europe, the United States and Canada. Trials can involve dozens to hundreds of patients, and multiple phases lasting several months.

To ensure the scientific integrity of the results, treatments are randomized and blinded to researchers. Data collected ranges from patient medical histories, medication dosages and laboratory results, to measurements of how the patient is responding to treatments, including any adverse events.

LEO Pharma designs and manages its clinical trials using Oracle Clinical, an application the company installed in 2002. The move helped increase productivity and data quality, executives say, but the company still faced delays getting data into the system in the first place—in large part because LEO still used paper case report forms (CRFs) to record data at each trial site.

“It takes a period of time to get access to the data with paper forms,” Clewlow says. “The forms have to be picked up and shipped back to the company; and the data needs to be keyed into the clinical data management system.” The wait for someone to visit the site can take as long as six weeks, he says, stretching out the trial’s timeline.

Going Paperless

To minimize such delays, the company recently moved to Oracle’s site-based electronic data capture (EDC) system—Oracle Remote Data Capture (RDC) Onsite. Instead of paper forms, researchers enter clinical data directly into a Web-based application located on a PC at the investigation site, often on the same day the patient

“Oracle Remote Data Capture’s convenient user interface has been well received by clinical research associates and employees at research sites. Remote Data Capture is stable, works well and has good support from Oracle.”

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is examined. The remote application integrates with the backend Oracle Clinical application, eliminating the need to ship paper forms and load data into the system later.

Since 2005, LEO Pharma has initiated more than 15 trials using Oracle RDC Onsite; eight more are scheduled for 2008. After that, the company plans on using Remote Data Capture for all of its studies. “We made a decision to move beyond the ‘perpetual pilot phase’ and go completely electronic,” Clewlow says. Today, about 850 researchers around the world use the Oracle RDC Onsite program for LEO.

Faster ‘Data Locks’, Better Data

How much faster is RDC Onsite compared to paper systems? While it’s hard to be specific since each study is different, Clewlow says LEO Pharma can now reduce processing time from the patient’s final visit to database lock—the point at which the study can be closed and unblinded—to just one to two weeks, down from the six to 12 weeks it usually takes with paper systems.

Beyond closing trials faster, companies find that EDC systems improve the integrity of the data collected. Oracle RDC Onsite comes with multiple quality checks that flag discrepancies and help researchers and data managers understand the reasons for follow-up changes. Cleaner datasets lead to fewer development and regulatory bottlenecks because pharmaceutical companies spend less time reworking the data—or repeating parts of the trial.

‘Lean CRFs’

To speed data collection even more, LEO Pharma redesigned its case report forms, removing unnecessary content and making it easier for investigators to complete. “We started listening to our investigators, our end users,” Clewlow says. “The reality was that we were loading too much extraneous information on the forms and nobody was using it.”

LEO Pharma’s new form is what Clewlow calls a “LEAN CRF” and says it is “far more attractive” for investigators entering the data. “It’s the same data but fewer pages to click on,” he says. The LEAN CRF initiative is part of his team’s ongoing efforts to improve system efficiency and end-user satisfaction.

Moving to Version 4.5.3: Easier Navigation, Zero Footprint

This year, the company rolled out the latest release of Oracle's solution, RDC Onsite 4.5.3, developed partly in response to feedback from users like LEO Pharma. The new version features easier screen navigation and a convenient zero-footprint design. Again the objective was to raise end-user productivity and satisfaction. Version 4.5.3 "looks more modern," Clewlow says. "It's so intuitive that you don't need to rely on all the support around it." Login times are shorter, he adds, and page openings are about 70 percent faster than the previous version.

The new zero-footprint design, requiring only a standard Web browser, makes version 4.5.3 easier to deploy. (Earlier releases required Acrobat Reader and Java Runtime plug-ins.) According to Clewlow, Leo Pharma's migration to the new version has gone smoothly, with the company completing the switch in about four months. "Trials are always ongoing, so you have to perform that upgrade quickly without impacting existing users and studies," he says.

Faster E-Submissions

Once the trial phases are completed, and the data locked, pharmaceutical companies are set to take the next step: submitting the clinical data and related documentation to regulators for review and approval. LEO Pharma works with a range of public authorities around the world, the most demanding being the U.S. Food and Drug Administration (FDA).

To speed regulatory review, the FDA encourages companies to submit new drug applications (NDAs) electronically. Among other requirements, e-submissions must include PDF versions of case report forms that are extensively cross-referenced, hyperlinked and bookmarked.

RDC Onsite facilitates the FDA's e-submission process by enabling companies to generate, in one step, a single PDF combining all CRFs for a patient. Each change made to the document is backed by electronic signatures that comply with the Food and Drug Administration's 21 CFR Part 11 Guidance. The consolidated document, known as a patient data report, along with an audit trail and discrepancy information, comprise a significant portion of the overall submission.

The PDF tool has proven to be a significant time-saver at LEO Pharma, helping the company avoid the hundreds of hours of document preparation that would be required to convert paper forms into an FDA-approved electronic document. “Scanning and bookmarking and hyperlinking is extremely time-consuming,” Clewlow says. “With Oracle RDC 4.5.3, you can generate a bookmarked and hyperlinked PDF in one step. So it’s a dramatic difference in time and money when it comes to submitting the data.”

Faster to Market

More important than trimming paper-handling, LEO Pharma expects electronic data capture to lead to faster drug development and approval. “At the end of the day, the main goal is to reduce clinical development time,” Clewlow says, which in turn should help LEO Pharma put its products on the market faster. A 2006 study by the Tufts Center for the Study of Drug Development found that the 10 companies fastest to deliver drugs to market used more electronic data management technologies.¹

The all-electronic system can offer other advantages, Clewlow says, such as increasing LEO Pharma’s capacity to handle more clinical trials a year. And he sees potential in the ability for researchers to probe the RDC system for ways to design better clinical trials. “People are seeing the opportunity to look at the data and analyze safety issues, for example, and to see areas that are not working and improve them for the next trial.”

LEO Pharma is among the world’s leading companies in the field of topical dermatology and parenteral treatment of thromboembolic disorders. LEO Pharma’s objective is to discover, develop, manufacture, and market effective, innovative pharmaceuticals that bring relief to patients and create steady earnings and growth.

¹ “Fastest Drug Developers Consistently Best Peers on Key Performance Metrics,” *Tufts Center for the Study of Drug Development Impact Report*, September/October 2006.