opentext™

Leading pharmaceutical company

Industry
- Pharmaceutical

Solutions
- OpenText™ Alloy™

Results

🚀 **Sped data cycle**
by approximately 70 percent

💲 **Cut operational expenses**
with changes in data structure

📈 **Increased capacity**
for clinical trials supporting
new drug pipeline

Leading pharmaceutical company improves clinical trial capacity and time to value

Global Life Sciences organization speeds flow of mega clinical trial data and supports timely, multi-trial analysis with OpenText Alloytimes and increases profit and growth with OpenText.

Leveraging OpenText Alloy enabled a leading pharmaceutical company to reduce time required to flow clinical trial data used for analysis from 125 days to 39 days.

A mega clinical trial strained existing clinical trial data infrastructure at this leading pharmaceutical company, creating inconsistent data flow for analysis. With the mega trial representing 50 percent of all clinical data collected for one year, data flow for other clinical trials was delayed, reducing the efficiency of the company's overall clinical trial program.

Although the pharmaceutical company's systems had the infrastructure in place to accommodate standard, small to medium clinical data trials, a mega trial brought new challenges that the company's legacy processes and tools, including its data-mapping tool, could not support. While even standard trials needed efficiency improvements in their data flow processes, the magnitude of the mega trial caused inconsistent data flow for analysis purposes. The company was using a single map for all data that had to be deposited in the clinical data repository. Because of the scope of the mega trial, the map size was extraordinarily large. Every time there was a change in the study, the company had to change the map, regardless of the size or significance of the change. Frequent changes meant there were continuous changes in the map, which prevented movement of data.

When enlisting the help of OpenText, the pharmaceutical company established clear and specific project objectives, including:

- Reduce the number of days required to flow clinical trial data used for analysis.

- Streamline the mapping of key clinical trial data to standard formats.

- Reduce costs by accelerating and streamlining processes and using offshore resources more efficiently.

- Enhance data quality to improve reliability and completeness of the clinical data repository.

- Redesign the data flow work process and technical mapping components to make them scalable.

- Implement a solution that would support the use of cloud-based services in future clinical trials.

OpenText analyzed the data flow problems and developed a complete solution, which included:

- New streamlined and optimized map development, testing and deployment processes.

- A hosted, scalable, run-time system capable of scaling to more than 200 clinical trials simultaneously.

- A library of standard forms-based maps that could be used repeatedly, enabling more efficient and consistent data flow.

- Integration to Study Data Tabulation Model (SDTM) compliant data sets.

- Training for the company's offshore contract research organization (CRO) on the newly developed system.

Based on the success of a six-month pilot of OpenText™ Alloy™, the pharmaceutical company decided to implement the solution for interface mapping in all future clinical trials. Since then, the company has realized a vast improvement in clinical trial data flow and additional business efficiencies, including:

- **Improved timing.** Cycle time was reduced from 125 days to 39 days.

- **Reduced costs.** The number of mapping resources required to support the trials was reduced due to changes to data structure and less reworking. Resource allocation improvements provided a further reduction in employee related operational expenses.

More trials can now be conducted simultaneously, supporting an increasing new drug pipeline.
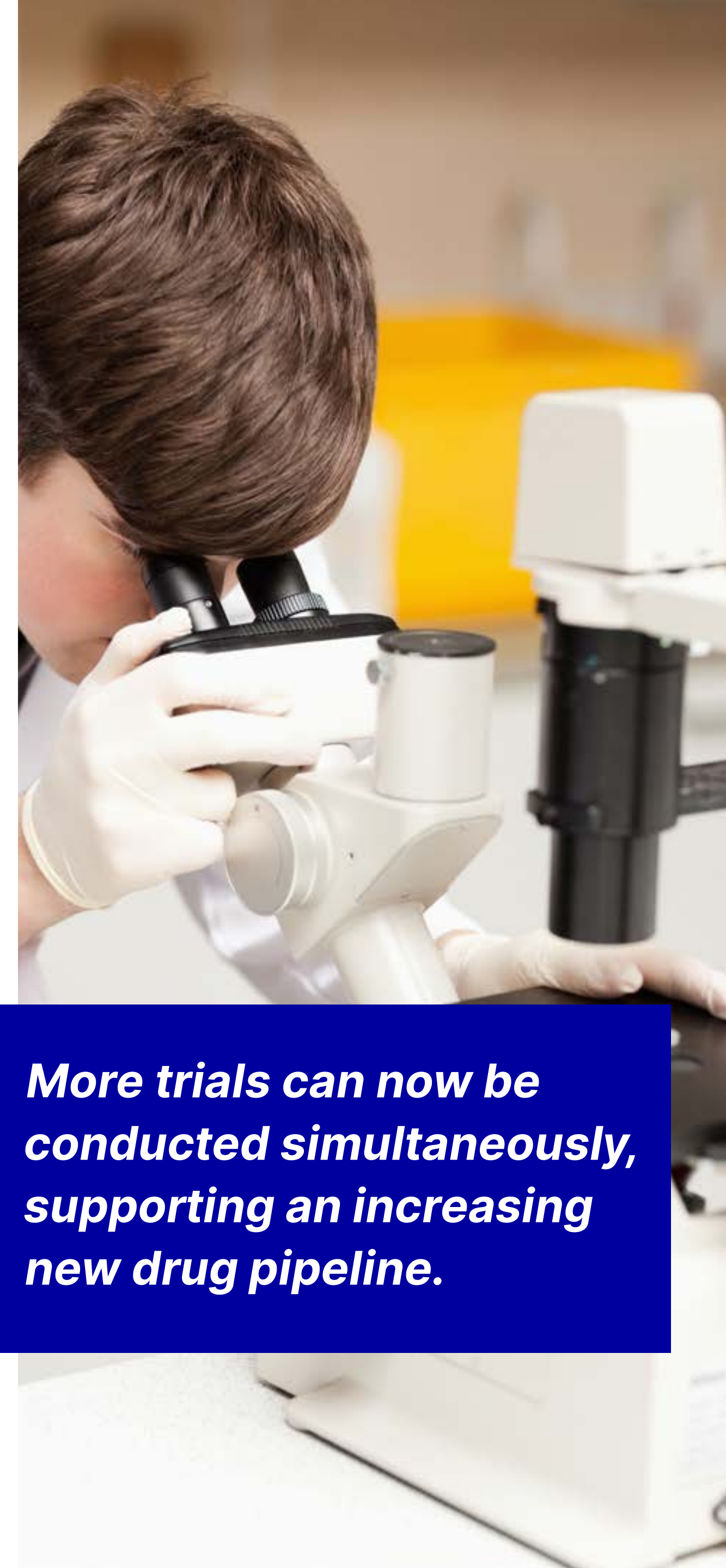
- **Accelerated data flow processes.** Map creation efficiencies reduced the average map development process time, and standardization encouraged more efficient utilization of staff resources.

- **Improved problem resolution.** Trending errors were reduced by replacing a sequential error identification and resolution process with a more dynamic process.

- **Greater capacity for clinical trials.** More trials can now be conducted simultaneously, supporting an increasing new drug pipeline.

- **Improved data quality.** Data manipulation decreased by 25 percent through automated error capture and handling.

- **Decreased disruptions.** Data flow disruptions reduced from an average 19 percent of active trial days to 6 percent.

- **Easier assimilation of acquisitions.** Easier support of clinical trial growth and volume that results from business acquisitions.

As the pharmaceutical and biotech industries continue to face new trends and challenges that hasten the tempo of business, innovation has become the most important precursor to improving profitability. The ever-increasing volume of data from clinical trials, as well as other sources, adds to the complexity of managing research and development. The leading pharmaceutical company's decision to invest in a scalable, flexible solution from OpenText that can continue to expand as the company's needs expand, positions it well to keep up with the accelerated pace of the industry.

About OpenText

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