SPEEDING CLINICAL TRIALS WITH BIOVIA PIPELINE PILOT

AUTOMATING AND STANDARDIZING CLINICAL TRIAL DATA MANAGEMENT FOR NEURODEGENERATIVE DISEASES

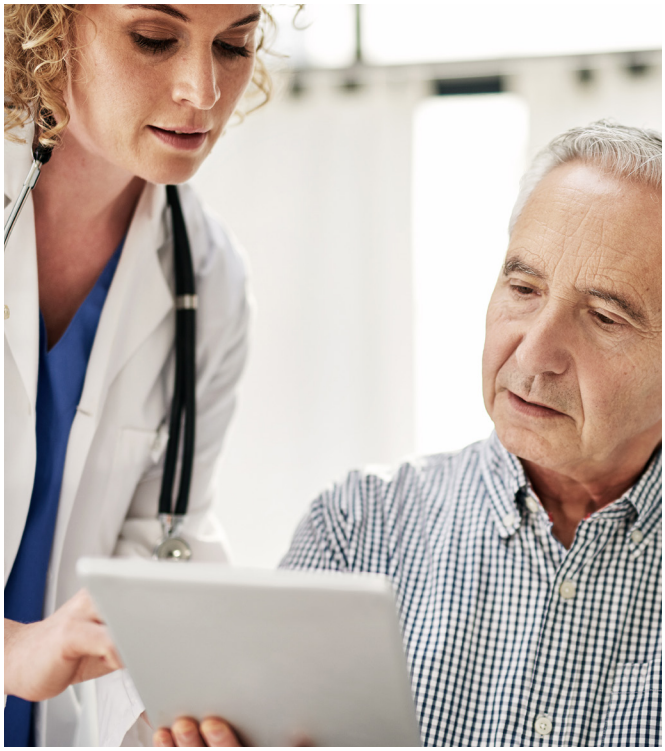
USE CASE

THE CUSTOMER: A LEADING DEVELOPER OF THERAPEUTICS FOR NEURODEGENERATIVE DISEASES

This BIOVIA customer has spent its long history tackling some of the most complex problems in medicine. Nowhere is this more evident than in their study of neurodegenerative diseases, which affect millions of people worldwide. Their innovative approaches to R&D, which include deep connections between their R&D staff and IT, seek to leverage every piece of data they generate, leading to discoveries which have significantly advanced the understanding of this field and yielded powerful treatments for their patients, although not without significant effort and time investment.

CHALLENGE: CLINICAL TRIAL DATA CAPTURE AND REVIEW

Managing clinical trials surrounding neurodegenerative diseases are inherently difficult due to the qualitative nature of the data provided. For example, instead of analyzing blood samples for traits like biomarkers which can be quantitatively measured, clinical researchers must rely upon "measuring" patient experiences, gathering data in the form of surveys such as memory tests. This empirical approach requires strict ontologies to ensure consistency across the data set and future analyses. As a result, the customer instituted an internal "review team" which would collect every test conducted by their clinical teams, check them for errors, log the errors into Excel, and generate site-by-site reports to identify areas for improvement. While this approach had potential, the sheer number of tests needed for review while managing multiple geographically-dispersed testing sites created significant logistical issues for the review team. The initial processes of the team relied heavily on paper and Excel-based methods to track when the tests arrived, who sent them, and what errors occurred, which in turn required a second set of reviews when generating reports. Previous attempts to create a custom solution with Excel had failed, lasting several months



"Using Pipeline Pilot, we were able to shorten our development time on the first build of our solution from a few months down to two days."

— Sr. Principal Research Engineer, A Leading Pharmaceutical Company

Challenge:

Inefficient and inconsistent managing of data collection and analysis from multiple clinical trial sites due to paper-based methods

Solution:

BIOVIA Pipeline Pilot for creating a common, standardized environment

Results:

- Estimated savings of 40 years of FTE work for clinical trial data management
- 20x increase in data Quality Control throughput
- Shortened "database lock" time for FDA submission from 4 months to 2 days
- Decreased variance in data quality across multiple sites
- Improved processes through streamlined site-by-site investigation

and wasting thousands of dollars. As a result, the clinical trial management team turned to the customer's internal development team, supported by BIOVIA Pipeline Pilot, for a solution.

SOLUTION: A STANDARDIZED SCALABLE ENVIRONMENT POWERED BY BIOVIA PIPELINE PILOT

BIOVIA Pipeline Pilot lies at the core of the customer's internal development team's application stack. Using its visual approach to application development, the team can rapidly build out workflows, automating the merging and integration of multiple data types and sources. Since Pipeline Pilot uses task-focused components in its workflow design, developers can better "think" like scientists when building a new application, fostering better collaboration between the developers and end users. Additionally, since these workflows are based on reusable components, future projects can leverage the same coding tools to speed up development time and standardize processes.

Using BIOVIA Pipeline Pilot, the team built out a web service to allow reviewers to load all their edits into a common, standardized environment. This service captures all relevant data within a common database and tracks data from the country and site level down to the individual investigators and anonymized patients. This service also tracks when reports are received and notifies the reviewers which tests are late or missing. Finally, the team can automatically generate reports and run analytics on demand to investigate potential areas for improvement. Using Pipeline Pilot, the initial build of this web service took approximately two days to develop, with a full version deployed in under four weeks. This service was able to scale with the program as well; as more patients entered the trial, a second version of the application, which had moved to a completely electronic environment, allowed clinicians on site to now directly submit their reports as a PDF into the database for review.

RESULTS: "RECORD-SETTING" TRIAL EFFICIENCY

Since implementing this Pipeline Pilot-powered web service, the customer recognized a significant improvement in the operational efficiency of their clinical trials. The common system eliminates the need for manual tracking of the timely submission of tests to the review team, and a common ontology for tracking errors streamlines quality control for the data review. This drastically increased the throughput of the review team: the first build increased the number of tests reviewed per person per day from five to 30; the second version increased the throughput to over 100 tests per person per day – an increase of over 20 times. This translates to a savings of 40 years of full time employee (FTE) work over the course of the trial. Additionally, by automating the reporting and analytics of the process, the review team is now able to carry out more detailed investigations faster, creating a more thorough feedback loop with their scientific collaborators on site. It helps to eliminate bottlenecks in the process sooner and significantly reduce statistical variance in the trial data. As a result of all these changes, especially since they could monitor the quality of their data in real time, the clinical trial team was able to shorten their "database lock" time, the amount of time it takes to do a final data quality check for submission to the FDA, from approximately four months down to two days, an internal record. The customer expects this to translate to billions of added revenue by the drug hitting the market earlier and bring significant relief to those patients who need it much sooner.

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Dassault Systèmes Corporate
Dassault Systèmes
175 Wyman Street
Waltham, Massachusetts
02451-1223
USA

BIOVIA Corporate Americas
BIOVIA
5005 Wateridge Vista Drive,
San Diego, CA
92121
USA

BIOVIA Corporate Europe
BIOVIA
334 Cambridge Science Park,
Cambridge CB4 0WN
England

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