CASE STUDY:

CLINICAL DATA QUALITY ASSESSMENT

ADDRESSING DATA QUALITY IRREGULARITIES TO KEEP APPROVAL ON TRACK

CHALLENGE

Maintaining complete and accurate clinical data can be difficult as biopharma companies sponsor clinical trials with larger patient populations, across more investigator sites around the world, and with more coordination needed with outside CRO partners.

When the EMA and FDA noted irregularities in a biopharma leader's major submission, the company turned to YourEncore to assess the issue, formulate a response, and ultimately, keep a blockbuster submission on track.

SOLUTION

Within 72 hours, YourEncore assembled a cross-functional team of experts in quality, data management and statistics to build a strategic plan for a comprehensive quality review of the data. The team reviewed the data for systemic issues, performed a thorough quality review of the findings, and provided recommendations for remediation.

By leveraging the expertise of a seasoned quality project manager and 12 functional experts – each with 25+ years of experience – the custom-built team was able to act quickly to keep the drug approval on track.

RESULTS

In a short time frame, YourEncore determined the extent of the data quality issues and identified a remediation plan. The pharmaceutical company passed the inspection and the

Based on the project's success, YourEncore has become an integral part of the biopharma company's quality organization, helping to preempt data quality issues before submission.

VALUE FROM EXPERIENCE

4 - 13 month

APPROVAL DELAY AVOIDED[2]

$2bil

ESTIMATED ANNUAL

[2]Source: Based on median approval delay findings from DataMonitor Study: "Complete Response Letter Trends and Influence on Approval Delays." January 11, 2013.

your encore®