A Need for Consistency
The US Affiliate of a top 10 European based pharma company came to the realization that their clinical development sourcing model had evolved within its late stage clinical operations function. In this model a blended approach to sourcing with reliance on insourcing, full service outsourcing, and functional service provider (FSP) approaches were all used based on study team decisions rather than overarching organizational strategy. Furthermore, the company did not possess a standardized approach to compare and contrast different sourcing models to allow objective performance benchmarking.

This divergent approach led to the organization retaining several non-core responsibilities which did not mirror industry best-in-class practices for clinical study execution. The result was the company’s inability to reproducibly achieve study milestones on time and within budget (Figure 1).

Challenge
Our client had a fragmented sourcing strategy within its late stage clinical development function. The operating model for this company did not mirror industry best-in-class practices for clinical study execution. The result was the company’s inability to reproducibly achieve study milestones on time and within budget.

Solution
Consulting at Quintiles leveraged its Clinical Development Health Check Diagnostic to benchmark the company’s clinical study performance metrics against best-in-class organizations. Such results help customers understand potential gains from altering their existing outsourcing strategy and resourcing model.

Results
This new outsourcing model allowed for a predicted increase of resource efficiency (approximately 40%) for its clinical operations staff, coupled with a significantly lower cost structure for clinical development activities, resulting in a lower likelihood of change orders, as well as improved cycle time performance.

Figure 1. A diagnostic was used to gauge the company’s ability to achieve planned study milestones. The outcome revealed that the company failed to meet all internal targets for its milestones and was in the lowest quartile based on industry performance.
Consulting at Quintiles leverages its Clinical Development Health Check Diagnostic tool to help clients understand potential gains from altering their existing outsourcing strategy and resourcing model.

Developing Strategic Alternatives
In order to analyze the client’s current practices related to clinical study execution, staffing and budget allocations, and utilization of external outsourcing vendors, Consulting at Quintiles leveraged its Clinical Development Health Check Diagnostic to benchmark the customer’s clinical study performance metrics against best-in-class organizations. This unique diagnostic tool is based on proprietary data within Quintiles’ databases of clinical development performance. The results help clients understand potential gains from altering their existing outsourcing strategy and resourcing model.

Recommendations were then developed for potential operating models that could be implemented based on potential strategic scenarios; these alternate strategies needed to be flexible, customizable solutions to accommodate studies requiring specialized capabilities.

Once the preferred strategy was selected Consulting at Quintiles guided the customer in developing high level transition plans enabling the client to quickly execute its preferred operating model within the greater organization.

The Path of Preferred Partners
The recommendation includes establishing this late stage clinical operations group as the center of excellence for clinical study outsourcing within the company. This was achieved through the implementation of a full service operating model with select “preferred” partners after defining the operational, financial and cycle time targets and metrics to monitor and track performance based on industry best practices. Figure 2 illustrates the client’s historical study start-up cycle time by sourcing strategy and the dangers of setting targets without first externally benchmarking performance.

The organization’s governance for implementation approved the recommendation. With adoption of this model, the organization’s study resource allocation model could be adjusted after rationalizing the roles and responsibilities that should be retained in-house versus those that should be transitioned to external partners.

Higher Efficiency, Stronger Performance
This new outsourcing model allowed for a predicted increase of resource efficiency (approximately 40%) for its clinical operations staff, coupled with a significantly lower cost structure for clinical development activities, resulting in a lower likelihood of change orders as well as improved cycle time performance. New targets were also defined and deployed for key business performance metrics driven by industry benchmarking of best-in-class processes as opposed to their lagging internal performance targets.

![Historical Start-up Cycle Time Study](https://example.com/image.png)

Figure 2. Following a full service outsourcing strategy provided more efficient cycle time performance. However, the client was still failing to meet its internal target of 180 days (which is less rigorous than industry standards of less than 120 days).

About Consulting at Quintiles
Consulting at Quintiles is a global business unit of Quintiles, the only fully-integrated life sciences services company offering clinical, commercial, capital and consulting solutions worldwide. This consulting group brings together an unmatched combination of deep pharmaceutical industry experience and extensive strategic consulting backgrounds and leverages the institutional knowledge of the broader Quintiles organization to design and implement leading biopharma development and commercialization solutions.

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