

The Power of Consolidation

How to Gain Efficiencies without Sacrificing Quality

Challenge

Managing multiple vendor relationships for data management and biostatistics functions created inefficiencies, particularly for an expansive oncology drug development program.

Solution

By suggesting a new operating model for the Functional Service Provider agreement, we created an integrated biometrics team with a single point of contact. Our streamlined flow of information led to better collaboration and greater productivity.

Results

Our centralized outsourcing model increased program efficiencies and quality without increasing resources.

Pressed to find greater cost efficiencies across the entire development cycle, biopharma companies are outsourcing more clinical trial services. But dealing with an extensive list of contacts is eroding their savings.

Even outsourcing separate functions can create process or communication silos of their own. It's a costly predicament at a time when every expense must be justified. Quintiles' answer: integrated services with one point of contact and streamlined management.

Streamline Vendors for Operational and Cost Efficiencies

Imagine the bedlam of dealing with 20 or 30 vendors. This leading pharma company was overwhelmed with more than 100 outsourced relationships. How could they achieve operational efficiencies and lower costs while juggling so many discrete contacts? Confident in Quintiles' capabilities, they asked us to implement a solution for both data management and biostatistics functions serving their oncology business unit.

We focused on a drug development program for one compound involving up to 20 concurrent studies and indications across Phase I – Phase IV. Adding to the complexity: Quintiles stepped into an ongoing process, requiring a quick transition of the knowledge and work done by previous vendors.

Merge Services, Centralize Point of Contact

We structured a Functional Service Provider (FSP) relationship that integrated data management and biostatistics into a dedicated biometrics team supporting this drug development program. Rather than concentrating on the disparate elements of the program, we approached the engagement as one comprehensive project.

By assigning the unique role of Biometrics Team Lead (BTL), we gave our customer's managers one central point of contact across every study. Because these functions did not overlap in the customer's organization, the BTL served as the hub of communication and strategy execution, streamlining the flow of information within the customer's teams, between the customer and Quintiles, and with other vendors. As a result, the customer increased on-time delivery of databases and significantly improved the quality of outputs.

Giving managers one central point of contact across every study streamlined the flow of information between the customer, Quintiles and other vendors. As a result, the customer increased on-time delivery of databases and significantly improved the quality of outputs.

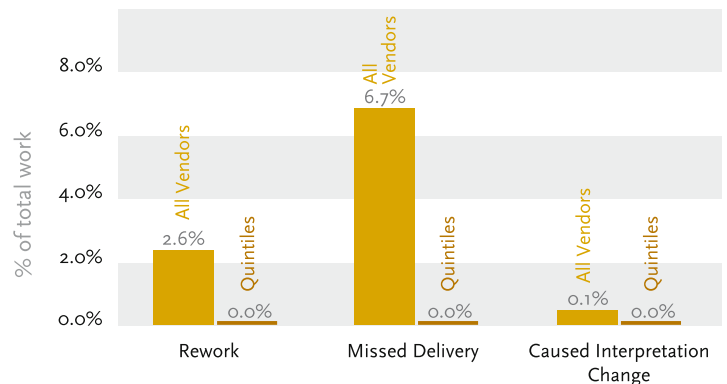
Leaders on the sponsor side championed the new model's advantages internally. Operational rollout meetings included representatives from each party to define clear objectives, risks and key performance indicators. The collaborative interaction allowed the teams to identify and resolve data-related issues quickly and provided them more flexibility to adapt to changing requirements and timelines over the course of the project.

Expecting a steep learning curve, Quintiles team members immersed themselves in the customer's business functions and internal processes. Although the sponsor's managers initially led projects, they soon came to trust Quintiles' staff as decision makers and problem-solvers on their behalf, freeing up managers from overseeing every issue. This shared management responsibility increased productivity across the drug program, removed time-sensitive bottlenecks and enabled faster operational scale-up. The sponsor team's confidence in this approach grew as they saw the seamless transition from their management to Quintiles' management. This added value transformed what could have been a vendor relationship into an alliance.

New Opportunities to Realize Greater Efficiencies

Embracing the sponsor's requirements, we tailored our centralized model to create a "best fit." Thanks to our customer's trust in our cross-functional team, they have greatly increased efficiencies, reduced the number of vendor contacts, and added a second drug program to the model. With the success of the model, Quintiles has identified and solved data issues prior to data delivery and has worked with the customer to increase the volume and complexity of studies included in the program. In fact, this model led to the rollout of another large-scale FSP relationship with this sponsor.

Consolidated FSP Model Improves Quality, Delivery



Source: Customer provided data

To measure the quality of delivery, the customer tracked key performance metrics from its more than 100 outsourced relationships, including percent of rework required, missed deliverables, and deliverables causing a change in interpretation. In all of these areas, Quintiles posted 0%, demonstrating that the new solution delivered improvements not just in efficiencies, but in overall quality as well.

Increasing Efficiencies without Sacrificing Quality

Oncology studies tend to be long-term, making knowledge retention and project continuity particularly challenging. Our strategic outsourcing model has helped keep knowledge retention rates above 95%. Retaining knowledge is helping the customer meet the heavy demand of ongoing deliverables for this program including quarterly safety reporting, formal interim analyses, blinded data reviews, monthly data evaluation reviews, dose selection analysis and final analysis reporting. Meeting these demands without the burden of internal oversight and increased resources helped achieve the critical goal of greater program efficiency.

Contact Us:

On the web: www.quintiles.com/clinical-services/biostatistics

Email: stats@quintiles.com