

Evolution from a hybrid outsourcing model to a novel full-service model



Enabling innovation within a long-term strategic partnership

Large pharma drug development organizations are increasingly looking for a true strategic partnership from their contract research organization (CRO) where the CRO takes full accountability and responsibility to lead the clinical study delivery with minimal resources from the client. This is a departure from the hybrid model most often applied where the CRO provides a support role to an internal clinical team. In this true full-service model, success depends on the CRO's expertise and ability to deliver true integrated services and a final clinical study report on time and with minimal input from the sponsor.

This case study describes how Fortrea successfully worked with a long-term pharma client to transform a well-established outsourcing and delivery model and implement a new integrated model with innovative approaches. Despite many challenges, the client and Fortrea were able to find new ways of working together and apply lessons learned, allowing both parties to advance the drug development process more efficiently.

Evaluating and evolving a partnership

After more than 10 years of traditional outsourcing, the client recognized there were significant inefficiencies in their clinical study outsourcing model, such as duplicate roles on the client and CRO side. With this realization, the client committed to finding a better model that would improve the process for their outsourced trials and deliver better and faster results in their clinical programs.

They asked Fortrea to assume increased accountability and autonomy for delivery, which would enable swift operational decision-making and enhance efficiency.

KEY TAKEAWAYS

- Analyzed resourcing data to identify inefficient processes and functions
- Jointly developed a change management plan to apply to all CRO providers
- Empowered CRO providers to assume additional responsibility and assigned oversight to the client
- Emphasized the benefits of culture over capabilities to help implement and reinforce the new delivery model
- Created an environment of shared values and continuous process improvement

Defining the baseline measure of success

At the outset, Fortrea supported the client by analyzing resourcing data, reviewing retrospective “time billed” by the client and CRO—both across the portfolio and at the study level—and identifying the most inefficient processes and functions. This allowed the client to provide justification and a business case for the change within their organization and to set targets for measuring efficiency improvement as new studies moved into the new model.

The baseline metrics revealed that the sponsor was billing 13% of the overall combined hours across their outsourced studies. Medics at the client site were identified as the largest with the greatest opportunity for improvement, billing 60% of overall medical hours, despite the fact they were outsourcing medical management to the CRO. Project management accounted for 10% of billing.

With these metrics, the client reduced their own internal staff, eliminating the redundant positions of data manager, clinical leads and regional project management support. They also implemented Xcellerate® Medical Review, which drastically reduced the number of medical staff assigned to a study.

Building a new outsourcing model and operating strategy

The client and Fortrea then identified a core team of functional leaders to build the new model accompanied by a change management plan. This team worked collaboratively over 12 months to conduct robust stakeholder and gap analysis and subsequently defined the future operational and contractual framework. Of note, Fortrea was the primary CRO service provider for the client. Therefore, the core model was built to be applied to Fortrea’s strategic partnership but could also be applied to other CRO providers.

The model focuses on empowering Fortrea to think, plan and act like the client. Fortrea was empowered to work with their own people, within their own processes and systems, while the client focused on oversight. By empowering Fortrea to take more responsibility for operational delivery, efficiency could be maximized with the use of more standard processes, reports and tools, which allowed teams to concentrate on delivering results.

Furthermore, an improved client oversight defined a new way of working with Fortrea. Here, the client could improve internal efficiency by trusting Fortrea to deliver their clinical trials, which would decrease client involvement in operations and deliver a lean, risk-based oversight model.

Supporting robust change management

Beyond the operational and process changes required, the most important challenge involved stakeholder management. Fortrea needed to assure the client’s internal teams that this was a positive change and ensure support from other CRO teams as needed.

The Fortrea joint senior executive committee acted as a true partner for this initiative. They directly engaged in the rollout by providing personal input into the training materials and developing the budget for branding and marketing. This involvement helped enable strong and effective endorsement as well as joint communication from the top down to strengthen both organizations.

In this approach, the committee emphasized the benefits to both the client company and the CRO. The benefits for the client teams included more trust: less micromanagement and more efficient oversight, which would result in fewer resources needed for outsourced trials and increased capacity for other internal development activities. For the CRO teams, the benefits included empowerment to take more responsibility for operational delivery and the ability to fully leverage internal efficacy with more standard processes such as reports and tools, which would allow CRO teams to concentrate on delivering results.

Guiding implementation challenges and cultural change

Core to the new delivery model was a new RACI, a responsibility assignment matrix, with definitions of clear, differentiated roles and responsibilities for the client and Fortrea staff. This was rolled out on all new studies awarded. The first two study teams working under the new processes were governed by strong communication, which included regular meetings with the core initiative team for guidance and predefined times when lessons learned were reviewed. Within a couple of months, the challenges were evident, and joint teams had to work together to find solutions quickly. These were all important steps to learn, and both parties remained transparent and flexible, adjusting to the model as needed.

After six months, the study teams faced several challenges. Although these were not unexpected, they undermined the reputation of the new model, causing people to question the direction of the partnership. In response, the initiative team rapidly created a communication plan across the partnership to reinforce the overarching objectives, emphasizing culture over capabilities. The team also held a face-to-face workshop to review the early adopter studies, identify successes and gaps and realign on the culture. This was a successful springboard for a renewed effort to enable success.

Understanding the importance of shared values and culture

At all stages of this project, the core themes of mutual trust, shared values and culture were emphasized. Understanding that such a change in delivery model would require a change in behavior for CRO and client teams alike, Fortrea incorporated formal team-building sessions at various stages. This started at the kickoff meeting, repeated at the one-year milestone and recently at the two-year milestone with a future annual team-building event scheduled. These meetings have provided a platform for open and honest discussions to support continued process improvement.

LOOKING AHEAD TO EVOLVE WITH THE CLIENT AND ACHIEVE SHARED GOALS

After two years, the operational framework is fully in place within both organizations as they support teams to succeed in a fully outsourced model. Fortrea is now empowered to take greater responsibility for operational strategy and delivery while the client is only responsible for oversight with a corresponding reduction in resource allocation on all outsourced studies. A master services agreement has also been adapted to support this model from a commercial perspective.

As new teams come onboard, both Fortrea and the client will continue to keep their cultures aligned, provide training and demonstrate the right behaviors to nurture their partnership and ultimately deliver results.

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