

The right outsourcing model is the one that truly meets your needs

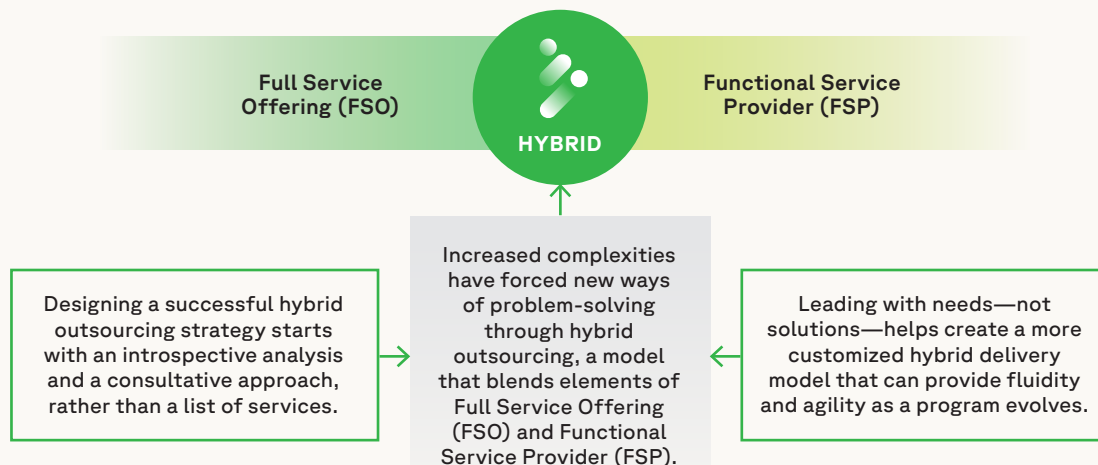
Understand the drivers behind an agile hybrid outsourcing model that works for you today, can flex for tomorrow and evolve with your company.

To help accelerate product development in today's industry, drug, device and diagnostic development sponsors often seek the support of contract research organizations (CROs). These outsourcing engagements provide sponsors with the specific skills, resources and experience needed at specific moments in their program.

As reported in a recent article in *Clinical Trials Arena*¹, biotechs especially appreciate the agility and focus offered by a flexible CRO. However, whether applying a Full Service Offering (FSO), Functional Service Provider (FSP) outsourcing model or a hybrid mix of each, a CRO must deliver an appropriate clinical trial portfolio that meets the sponsor's specific organizational goals.

When helping sponsors choose an optimal outsourcing strategy or reconfigure their current strategy, Fortrea first engages sponsors with a consultative model to assess how they approach outsourcing. We start with three key questions that can help define the right service delivery model and ensure that outsourcing seamlessly aligns within the unique requirements of a program or project.

1. Will a hybrid outsourcing model fully meet your organization's needs?
2. What if you start with a consultative approach to fully evaluate your own needs—before selecting your outsourcing model?
3. Will your outsourcing partner be able to deliver on your needs in the future?



A different approach to hybrid outsourcing

Will a hybrid outsourcing model fully meet your organization's needs?

At its core, the term “hybrid” combines different outsourcing models to meet a business need, but there is no universal hybrid solution as each varies based on a sponsor's requirements. While hybrid outsourcing across our industry isn't a new concept, we believe the drivers behind selecting a customized, agile outsourcing strategy have evolved.

The current challenges of conducting clinical trials have increased exponentially as new complexities need to be solved, such as reducing patient and site burden, incorporating diversity and inclusion and working with technology advancements. Today's drug developers must look beyond solving the so-called “triple constraints” of speed, quality and cost through outsourcing. As a result, hybrid models, which blend Full Service and FSP offerings, have emerged over the last decade.

Fortrea advocates for outsourcing solutions that are crafted and tailored based on specific needs, rather than the selection of a set of pre-packaged services. We believe that determining the best fit for outsourcing starts with an introspective analysis to help a sponsor think about their:



Tolerance for trusting outsourcing

The level of trust required and desired level of internal control (or need for duplicative functions)



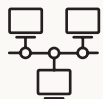
Ambitions for growth

The need to develop and retain internal experience and/or expand expertise to support new therapeutic areas or geographies as their pipeline evolves



Ability to change

The willingness and capacity to implement changes to an operational model



Technology integration needs

The need to integrate with and/or augment existing systems, technologies and data to enhance service delivery



Stakeholder buy-in

The ability to secure internal stakeholder buy-in on a selected outsourcing strategy

By completing this important self-reflection, we have found that sponsors are more prepared and better able to articulate both their needs and their constraints to their outsourcing partners. This process also helps:

- **Develop trust** and initiate more collaborative relationships between sponsors and their selected outsourcing providers
- **Recognize needs** that shape an outsourcing strategy and develop a commercial construct that truly meets an organization's goals, drives value and aligns incentives
- **Promote efficiencies** through a model that can help find opportunities for cost savings
- **Enable quality** through standardization
- **Reduce whitespace** to accelerate the timelines

With hybrid outsourcing, these goals can be achieved, for example, by implementing a centralized function, helping optimize a process or outsourcing non-core functions or tasks. Here, disruption can be minimized through a well-crafted transition plan that supports change management.

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What if you start with a consultative approach to fully evaluate your own needs—before selecting your outsourcing model?

We have found that the most effective outsourcing models take shape through collaborative consulting with potential partners—prior to development of their RFP. This ensures a more tailored strategic solution that, in many cases, has resulted in a hybrid offering.

We're continually optimizing our processes and gathering lessons learned to determine how hybrid outsourcing can be more effective for our partners. We've found the most success with outsourcing when we can help our partners outline their requirements, fully understand their options, recognize the value each strategy brings and evaluate their best path ahead.

Our consultative approach involves discussing key questions together, such as:



- What challenges are you facing (such as technology limitations, staffing flexibility, rising costs, etc.)?
- How do you envision your outsourcing strategy will help address these current limitations, needs or constraints?
- What are your internal capabilities and resources to manage the project?
- Which outsourcing strategy is realistic for your organization and best aligns with your internal infrastructure?
- How can your outsourcing strategy look beyond your organization's needs to also meet the needs of sites and patients to promote a better experience and execution?
- Does your technology platform optimize communication and decision-making?

We believe hybrid outsourcing must be approached by starting with the needs of the sponsor, rather than the services of a CRO. By consulting with a sponsor—before they submit an RFP—we are better equipped to design and present a more targeted outsourcing strategy. Not only does this strategy incorporate the ongoing demands for speed, quality and cost with current requirements but it also offers flexibility to accommodate future needs.

Will your outsourcing partner be able to deliver on your needs in the future?

We recognize that needs, which sponsors are trying to solve for today, will not remain the same over time. Sponsors need to ensure their selected outsourcing partner is inherently designed to offer flexibility throughout a partnership and can dynamically adjust their services.

To agilely respond to changes in our industry and best meet the needs of our customers, Fortrea has implemented significant changes in our organizational structure. Instead of FSP and Full Service housed within their own business “verticals,” we have restructured our hybrid delivery with a “horizontal” framework, which enables us to:

- **Enhance flexibility across our project and operational delivery teams and better align with our partners’ current and future needs**
- **Promote fluidity and agility in our hybrid delivery services to bring in the right talent and resources—and swiftly adapt to change**
- **Drive consistency while maintaining quality throughout the lifecycle of a clinical trial or program**
- **Deliver needs-based outsourcing experience that is centered on proactive problem-solving and addressing the ongoing needs of sites and their patients**
- **Improve overall satisfaction by continually optimizing and evolving to meet unique challenges**

The power of an agile partnership

Hybrid outsourcing models often facilitate the development of longterm collaborative partnerships between customers and service providers. These collaborations can lead to shared learning, continuous improvement and mutual success over time, driving operational efficiencies and potential cost savings.

While a CRO’s business configuration is often behind the scenes, we recognize the importance of transparency of our internal architecture with our partners. We believe our purpose-built structure is the key to maximizing our operational flexibility and more broadly opens the available delivery solutions. By delivering our hybrid services seamlessly—without organizational boundaries—we strengthen our ability to deliver more integrated, aligned hybrid models for our partners.



Sharing our vision with you to enable more effective hybrid outsourcing

Hybrid outsourcing isn't new, but how we approach it at Fortrea is unique. Custom hybrid blends have served as the foundation of some of our longest-standing partnerships and have proved instrumental by effectively addressing current requirements while simultaneously maintaining a strategic focus on the evolving needs of the drug development industry.

Our pragmatism and experience in assessing the most fitting solutions and services helps us design an outsourcing strategy that encompasses the best interests of sites and patients—and provides flexibility to meet your current and future needs.

Fortrea
Together, exceptional is possible

Schedule your complimentary consultation

Learn more about Fortrea's approach to outsourcing and how to clearly define a strategy that ultimately adds value to your organization. Click on the **REQUEST A FREE CONSULT** button at fortrea.com to start the conversation.

Together, let's develop an outsourcing model that is **Designed Around You.**[®]

References

1. Beaney, A, *Pharma and biotech concerned about the stability of large CROs, survey finds.* <https://www.clinicaltrialsarena.com/news/pharma-biotech-concerns-large-cro/?cf-view>. Accessed Feb. 12, 2024.

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