# Fit-for-purpose outsourcing models:

## Adapting to a world of untapped innovation and emerging risks

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# Foreword

The nature of clinical development outsourcing partnerships continues to shift. Urgent needs posed by increasing complexity, efficiency pressures and the operational demands of clinical trials are presenting huge opportunities and challenges for biopharma. In response, clinical development outsourcing strategies are evolving with sponsors increasingly blending functional service provider (FSP) and full-service outsourcing (FSO) models into bespoke, hybrid approaches.

With a substantial increase in trials over the past five years and significant geographical diversification, biopharma companies face new criteria when considering an outsourcing strategy. What are the best ways to optimize trial design, enhance patient-guided development, and leverage technology effectively? How much control would you like to retain over day-to-day operations? How much flexibility will you need in staff resourcing? What technology, processes and regulatory strategy will support your path forward?

More bespoke models are emerging to answer these questions and provide sponsors with the agility to adapt to a world of untapped innovation and emerging risks, thereby building resilience. With a focus on prioritizing patient and investigator needs, outsourcing strategies are also pivoting to support sponsors' in strengthening their relationships with investigators and key opinion leaders. Determining the right balance of control and accountability is now a critical success factor in outsourcing partnerships.

Whether opting for a full-service model, an FSP approach, or a bespoke, hybrid solution, we can help you prioritize your desired operating model while weighing the limitations and benefits of each approach. We've designed this playbook as a starting point to provide you with a more holistic view of outsourcing, guiding you through key considerations that will determine the framework of your approach, aligning with your organization's goals, risk tolerance, and capacity for change.

At Parexel, we're enablers of innovation. Our goal is to help you choose an outsourcing model that evolves with your needs and responds to market dynamics and uncertainties with a focus on innovation and emerging opportunities.

**Jenny Denney**
Executive Vice President, Global Head FSP

Many biopharma companies are familiar with two primary models for outsourcing: Full-service outsourcing (FSO) and Functional service provider (FSP). With FSO, biopharma companies outsource all aspects of clinical trial management, including project management oversight and functional staffing, to a single CRO. The FSO model is effective in many situations including studies where:

- Internal infrastructure is constrained (due to factors like a sudden increase in pipeline or a shift to new geographical locations without an established footprint)
- High flexibility/variability in resourcing is required (such as vaccine trials)
- Specialized investigator site relationships or operational expertise that the sponsor has not yet cultivated (for example, in a new therapeutic area).

With FSP outsourcing, a CRO handles specific functions or services across a large portfolio of clinical trials, integrating seamlessly with internal teams. FSP enables sponsors to:

- Achieve cost containment and assurance of supply by building teams in geographies where the sponsor doesn't have a footprint
- Scale resources up or down to support shifting pipeline priorities
- Achieve a cost-effective approach for limited outsourced services
- Maintain consistency across studies by retaining the same functional team for multiple trials or programs

In today's dynamic drug development landscape, selecting the right outsourcing strategy is critical for biopharma companies as they strive to bring treatments to market swiftly and efficiently. This playbook examines FSP, FSO, and hybrid models, with insights for choosing the optimal approach for clinical development goals and ultimately, success.

# Outsourcing models have evolved to a bespoke continuum

## Full service outsourcing

End-to-end trial planning and management

- **Comprehensive solution:** Sponsors outsource all aspects of clinical trial management to a single CRO.
- **Reduced operational burden:** Sponsors focus on core competencies while the CRO handles all trial related tasks.
- **Streamlined communication:** One point of contact manages all trial activities from the CRO.
- **Expertise across multiple operational functions:** Access to a wide range of specialized knowledge and skills.
- **Cost efficiencies and resource optimization:** CROs leverage global resourcing strategies to optimize resources in trial delivery. Particularly valuable in large-scale trials for which the sponsor lacks the internal infrastructure.
- **Technology and Innovation:** CROs' established infrastructure and technological investments drive quality improvements and process efficiencies.
- **Data-driven strategic feasibility:** Potential risks and opportunities are identified early-on through strategic site selection and a patient-guided approach.

## Functional service provider

Ranging from staff augmentation to managed staff and unitized performance-driven delivery models

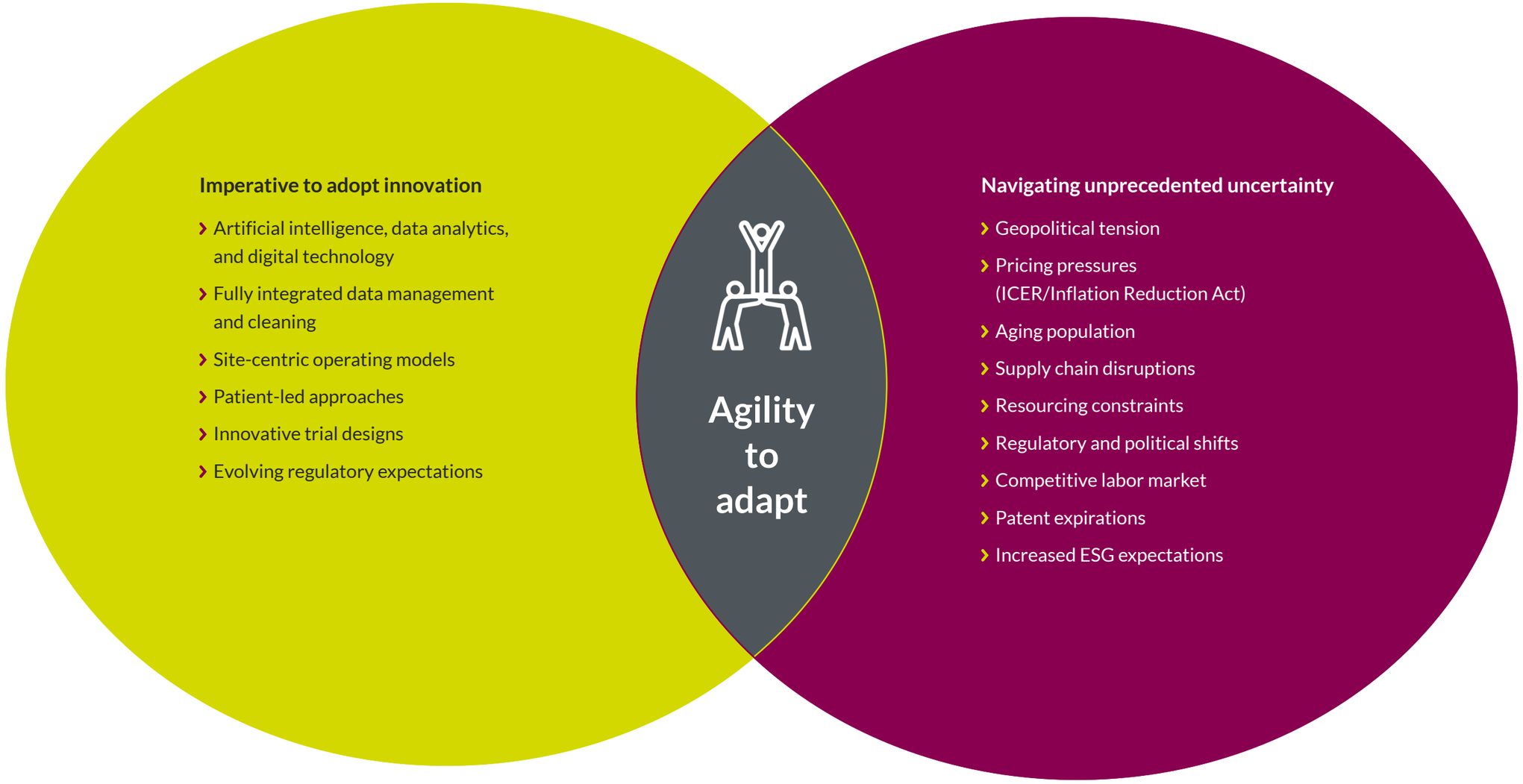
- **Flexibility:** Specific functions scaled up or down as needed. Sponsor has ultimate control over deployment of staff according to pipeline priorities.
- **Control:** Sponsors maintain oversight of critical functions while outsourcing non-core functions.
- **Cost-effective:** Dedicated functions and talent drive cost efficiencies at scale.
- **Dedicated specialized expertise:** Sponsors access critical functional expertise and talent that best fits their organizational culture.
- **Integration with existing processes:** CRO or sponsor systems and SOPs can be leveraged depending on model preferences and needs.
- **Consistency across studies:** Maintains the same functional team across multiple trials or programs.
- **Global coverage:** Ensures access to specialized talent while helping to de-risk global footprint decisions.

## Hybrid, bespoke models

Combines the best aspects of FSO and FSP models

- **Adaptability:** As needs change over time or across different studies, the outsourcing strategy can be adjusted.
- **Risk mitigation:** Avoids over-reliance on a single outsourcing model providing agility to manage uncertainties.
- **Scalability:** Specific functions can easily be scaled up or down while maintaining a core full-service arrangement.
- **Transition support:** Facilitates smooth transitions between different outsourcing models, enhancing efficiencies and flexibility.
- **Systems and processes:** A combination of sponsor and CRO systems and processes provides greater agility.
- **Optimization of resources:** Allows sponsors to leverage internal strengths while filling gaps with external expertise.
- **Balancing control and efficiency:** Sponsors maintain control over critical functions while benefiting from the efficiency of full-service outsourcing in other areas.
- **Collaboration:** Cross-pollination of staff between outsourcing models cultivates a talent pool with deep sponsor knowledge.

# Adapting to a world of untapped innovation and emerging risks



The clinical development industry stands at a critical juncture. Economic pressures, talent shortages, sustainability concerns, and intensifying competition for sites and patients are straining the industry's ability to bring new therapies to patients. At the same time, emerging technologies, data applications, and process innovations offer promising solutions to revolutionize clinical development.

While FSO and FSP models provide a foundation for structuring an outsourcing partnership, to thrive in this competitive landscape, FSP adoption is increasing. By outsourcing entire functions, FSP provides sponsors with the agility to quickly adapt to industry challenges and shift areas of focus to accelerate drug development.

However, the shift toward FSP isn’t a complete pendulum swing away from FSO. Rather, it's an evolution towards a more balanced approach offered by bespoke, hybrid approaches that strategically combine the strengths of both models. A core part of the success of the hybrid approach begins with selecting an operational model that optimizes cost and timelines based on specific needs such as therapeutic area, geography, technology and site relationships.

This requires sponsors and contract research organizations (CROs) to partner in a collaborative way that balances short-term needs with long-term objectives. The move away from a more transactional service model to a strategic, tailored model enables innovation and efficiency while adapting to the sponsor’s specific needs to complement existing in-house capabilities and ensure the optimal timing of critical activities.

# Achieving a more strategic, bespoke model

Success is achieved by attaining the right balance between FSO and FSP. When customizing a partnership structure, we ask the sponsor to consider the following key questions.

1. **How much control do you want to retain?**
   Sponsors and their partners should align on how they will handle data access and decision-making power from the outset. For example, a sponsor may prefer to retain control over critical functions, requiring the CRO to use sponsor SOPs. In other cases, a sponsor might want to manage all study data in their own clinical trial management system or serve as the continuous point of contact for key investigators in order to build relationships.

2. **In what ways do you need to augment resources and expertise?**
   A CRO partnership gives sponsors access to flexible staffing, with the ability to quickly scale resources as research progresses or changes. When choosing an outsourcing model, companies should carefully consider their pipeline and anticipated workload. FSP-based approaches require longer-term commitments but can provide significant cost efficiencies for robust pipelines. Outsourcing also allows sponsors to tap into therapeutic- and indication-specific trial expertise. Studies for rare diseases and specialized therapeutic areas, for instance, may benefit from input from CRO experts.

3. **Will you be working in new geographic areas?**
   Clinical trial infrastructures in many countries are quickly evolving, requiring a footprint in regions where a strong foundation may not exist. Geographic expansion and diversification are critical components of the transformation across the industry. This approach serves two key purposes: accessing target patient populations in new regions and establishing hubs to help ensure supply and stabilize the cost of your talent pool in support of centralized trial operations.

4. **What are your plans for developing an agile, clinical trial workforce for the future?**
   The clinical trial landscape is evolving, demanding new competencies from professionals. Traditional roles like clinical monitoring are transitioning towards data science and site relationship management. Continuous upskilling is crucial to maintain a workforce capable of executing future trials effectively. Best practices now include forming agile outsourcing partnerships with a focus on developing a diverse talent ecosystem. This approach ensures access to a wide range of skills and adaptability to changing industry needs.

# Outsourcing as a long-term investment

Biopharma companies are increasingly approaching outsourcing as a long-term shared commitment with a focus on agility and innovation for the future. As a result, sponsors and CROs are entering into collaborative partnerships in which both take a long-term view of the total cost of the work being conducted. With the optimal outsourcing strategy, biopharma companies can streamline research, capitalize on outside expertise, and bring innovative treatments to patients who need them faster.

One example is the creation of asset/therapeutic area-aligned centers of excellence for all pre-study activities. These centers bring together sponsor and CRO data, subject matter experts, and insights to reduce white space, accelerate enrollment, and improve trial success. The approach emphasizes the importance of strategic feasibility assessments, protocol optimization, and asset planning to ensure that resources are allocated efficiently and development plans are optimized.

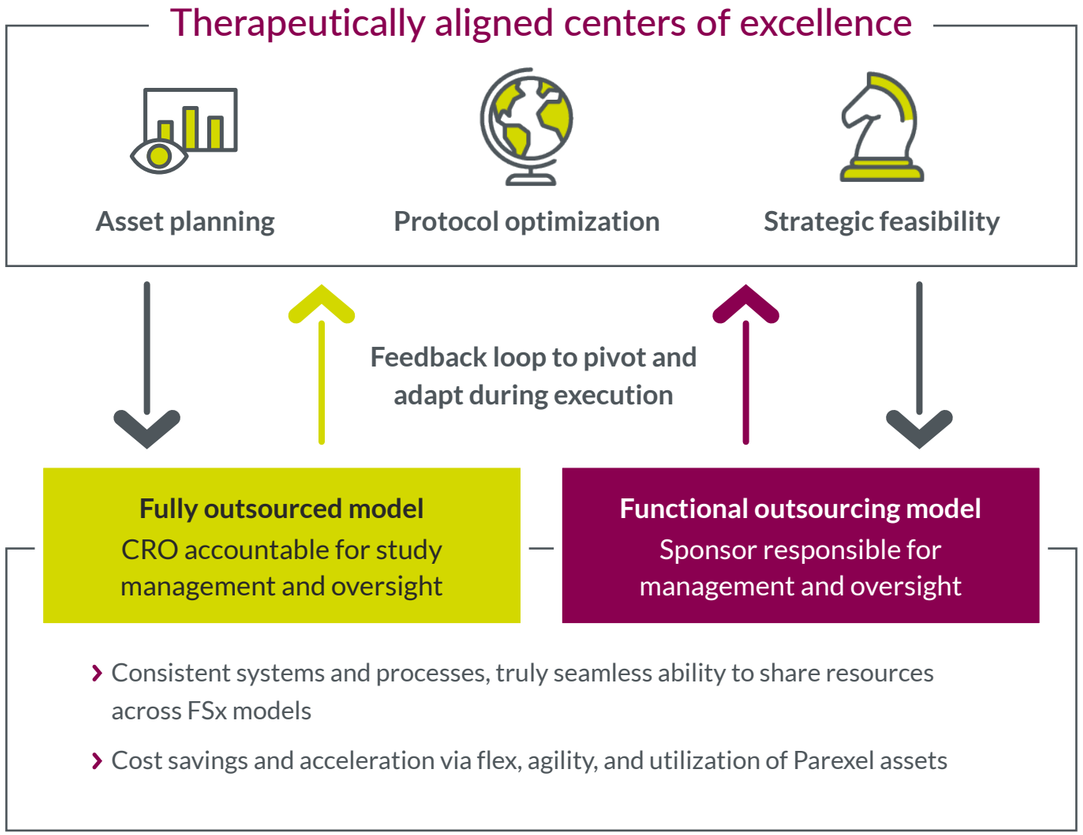
Through an agile FSO-FSP interoperable delivery unit the model creates a holistic team of talent, oversight, quality, and training, combined with a resource pool for flexibility, productivity and access to diverse geographies. The ability to transition resources across FSO and FSP models would provide sponsors with scale and agility to build resilience through a feedback loop that allows for pivoting and adapting during execution, ensuring that strategies remain aligned with changing circumstances and emerging data.

# The new gold standard in strategic sourcing metrics: Total cost of ownership

While the traditional focus on bill rates and unit costs in building FSP rate cards may achieve an "apples to apples" cost savings, a new holistic approach (right), takes a more comprehensive view of the entire clinical development process. Through cross functional strategic partnerships that focus on reducing hours and effort needed (rather than the cost of hours), the model combines FSP and FSO strategies to:

1. **Optimize clinical development plans:** Reduces the burden on investigators and patients
2. **Increase productivity:** Leverages technology and process improvements
3. **Establish metrics to evaluate indirect factors of success:** Considers timelines, site efficiency, and novel study designs

This shift toward more bespoke models, similar to the model presented here, represents a significant evolution in biopharma partnerships. By taking a more holistic, strategic, and flexible approach, these new ways of working together will improve not just cost-effectiveness, but also the overall success and efficiency of drug development programs.



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