

**Strategic outsourcing
redefined:** Building
partnerships that
propel innovation



Forward

In today's complex clinical trial landscape, agile outsourcing solutions are emerging to help bring innovative products to market more quickly and cost-effectively. At Parexel Biotech, we understand that your needs are unique, whether you're an emerging biotech seeking full-service support or a mid-size to large biotech exploring functional service provider (FSP) solutions.

That's why we've moved beyond the one-size-fits-all outsourcing approach to offer a holistic view that considers all functions within your organization and the interconnected nature of our industry.

We'll work with you to develop a comprehensive outsourcing plan that delivers cost efficiencies, helps you demonstrate proof of concept, and generates the evidence necessary to earn investor confidence, regulatory approval, and market access, should you choose to commercialize.

With Parexel as your strategic partner, you gain:

- › Access to comprehensive therapeutic expertise backed by proven study experience
- › Increased resource flexibility across a global network
- › Cost efficiencies through optimized resource allocation
- › A **partner** committed to both operational excellence and comprehensive strategy

This playbook will walk you through key considerations for developing an agile outsourcing strategy that amplifies your strengths and maximizes your opportunities.

Let's start a conversation about how we can support your journey.

Sincerely,



Jenny Denney

Jenny Denney

Executive Vice President, Global Head FSP

A holistic approach to outsourcing

Biotech companies, as life science innovators, face unique challenges and opportunities. While their agility and specialized expertise continue to fuel promising pipelines and new therapies, they must carefully navigate possible resource constraints and scale limitations.

To thrive in this competitive landscape, many companies are pivoting towards a more strategic, holistic outsourcing approach that moves beyond the traditional full-service model and better aligns with their long-term goals. With insight into the current and evolving market landscape, a CRO can help you realize product value and commercial opportunity in early development and throughout the product development cycle.




Whether seeking to out-license a compound, enter the clinic, reach proof-of-concept or commercialize decisions made at the asset level will shape the structure of your outsourcing model:

In **full-service outsourcing (FSO)**, the CRO reduces the sponsor's operational burden by conducting the clinical study, providing the functional downstream services, including project management oversight and team staffing. FSO is well-suited to sponsor organizations that lack a clinical services infrastructure.

In **functional service provider outsourcing (FSP)**, a CRO handles specific functions or services across clinical trials, integrating seamlessly with internal teams to bridge resource gaps. Sponsors access critical functional expertise and talent that best fits their organizational culture, with CRO staff embedded into their teams. This model is often used to support high volume core functions. While sponsors maintain ultimate responsibility for deliverables, they benefit from reduced day-to-day oversight requirements, allowing their internal teams to focus on strategic priorities.



While pure FSO and FSP models work for some biotechs, we've found that many may benefit from a bespoke hybrid approach combining the best elements of both. The optimal model – whether full-service, FSP-based, or hybrid – depends on expected pipeline growth, the number of studies and indications, and clinical development stage.

 Full service outsourcing End-to-end trial planning and management	 Functional service provider Ranging from staff augmentation to managed staff and unitized performance-driven delivery models	 Hybrid, bespoke models Combines the best aspects of FSO and FSP models
<ul style="list-style-type: none"> › 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. 	<ul style="list-style-type: none"> › 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. 	<ul style="list-style-type: none"> › 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.

Designing the model with the end in mind

To create a fit-for-purpose outsourcing solution, begin with the end in mind.



What is the size of your pipeline?



Do you intend to bring your product to market or will you pursue a licensing deal earlier in development?



Do you have all of the required functional expertise in-house?



Will your clinical operations infrastructure help you deliver?

Based on these core questions, the following key challenges and opportunities will guide your outsourcing strategy and help you design a partnership that amplifies your current capabilities by providing solutions that scale to meet your needs.



Core strengths

Rather than building out the procedures, systems, and large teams necessary for conducting studies, biotechs may opt to outsource clinical services — leveraging a full-service model that reduces operational burden and allows the sponsor to remain focused on the science, drug platforms, and other core capabilities. By taking this approach, companies can eliminate the significant time and capital investment required to develop clinical operations expertise, quality management systems, and global regulatory knowledge.



Geographic footprint and global expertise

Many biotechs are centralized in a single location, with limited or no presence outside of home countries. In such cases, hybrid outsourcing allows a sponsor to use an FSP-based approach in its primary location, where resources are strongest, and opt for a hybrid approach in countries where clinical trials are critical but internal resources are insufficient. This blended strategy accommodates geographical diversification and growth without extensive internal expansion. Biotechs can also reduce costs and create efficiencies by leveraging a CRO's established presence in lower-cost countries, taking advantage of the CRO's expertise, infrastructure, and relationships.



Technology preferences

The choice of model should align with a company's current technology capabilities and long-term strategic technology vision.

- Would you prefer to build and maintain your own systems as provided by FSP and common in a hybrid model? Or could you benefit from CRO-provided innovation that can be part of both FSO and hybrid models? Your choice should be guided by your current capabilities and long-term strategic technology vision. In-house technology solutions give sponsors greater control but require ongoing investment and maintenance. This approach can be valuable for sponsors with highly specialized workflows or proprietary systems. On the other hand, using CRO-provided systems eliminates technology maintenance burdens and offers access to innovative technologies and scalable solutions that have been refined across numerous trials.



Adapting as you mature

Emerging biotech companies may opt for full-service outsourcing to support a smaller pipeline of one or two trials or to supplement their team in anticipation of portfolio growth. However, as they grow their portfolio and capabilities, these companies may want to explore FSP-based solutions. To facilitate this transition, Parexel helps identify areas in which functional outsourcing can be implemented effectively without disrupting existing operations. This approach enables biotechs to balance internal capabilities with external support.

As your biotech organization evolves, consider FSP outsourcing for:



Staff augmentation, which allows you to expand your team without the complexities of direct hiring.



Biometrics, including data management, biostatistics and statistical programming, and medical writing, which can be efficiently and cost-effectively managed through functional outsourcing because of its relatively stable resource needs.



Regulatory and safety operations, providing access to domain expertise while reducing infrastructure costs.

FSP outsourcing offers increased resource flexibility across different regions with dedicated functions and talent to drive cost efficiencies at scale. With a view into common challenges, CROs like Parexel have the expertise and scale to identify opportunities to optimize the FSP model. Parexel works collaboratively with your organization to design a bespoke outsourcing model that aligns with your unique strategic objectives, technology infrastructure, and resource capabilities. With this consultative approach, biotechs can gradually integrate FSO and FSP approaches with a custom model that helps balance control, technological innovation, and access to expertise.



Enlisting the ideal partner

The right CRO partnership transcends traditional outsourcing – it becomes an extension of your vision and capabilities. When evaluating potential partners, consider strategic alignment:

- › **Long-term compatibility:** choose a partner whose capabilities not only address today’s challenges but evolve alongside your pipeline and growth trajectory.
- › **Adaptive partnership models:** your ideal CRO should offer flexible engagement frameworks that seamlessly scale with your changing needs—from early development through commercialization.

Parexel’s specialized biotech unit combines tactical precision with strategic foresight. Our approach:

- › Leverages decades of biotech-specific experience across therapeutic areas and development phases
- › Provides access to seasoned experts who anticipate challenges before they emerge
- › Delivers customized solutions that amplify your team’s strengths while filling capability gaps

We don’t just execute protocols – we collaborate as true partners invested in your success. Our team works alongside yours to uncover innovative approaches that accelerate timelines, optimize resources, and ultimately bring life-changing treatments to patients faster.

››› Evaluating outsourcing approaches? [Let’s have a conversation and explore the best model for your goals.](#)

>>> Could a partnership like that help you bring
breakthrough innovations to life?

*With Heart*TM

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