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How Mixing FSP and FSO Models Bring Agility to Modern Clinical Development

Clinical trials are becoming longer, costlier and more complex, but a growing number of sponsors are finding agility in a hybrid approach.

By Les Enterline | 12/15/2025

Clinical development has always been a complex process, requiring various stakeholders including pharmaceutical and biotech companies, patient groups, clinical research organizations (CROs) and regulatory bodies to collaborate over a years-long initiative to bring safe, effective therapies to market. Escalating costs, increases in patient participation burden, and increasing clinical trial timelines are amplifying long-standing issues around growing complexity, forcing trial sponsors to rethink their clinical development models.

Strategically selecting the right operating model to support this process has far-reaching impacts and can help maximize quality, operational success, and financial efficiency. For many organizations, a path forward supported by a CRO that embraces mixed models combining functional service provider (FSP) services with full-service outsourcing (FSO) models offers the ideal blend of control, flexibility and accountability for clinical development needs.

The current state of clinical research

Today's clinical development environment is fast and competitive, and it's more complex than ever. Trials themselves reflect a growing number of procedures, more robust data collection, and everevolving rules in every region where they are conducted. Protocols include 70 percent more procedures, data points have increased by 157 percent per trial, and timelines are now approximately 20-30 percent longer than a decade ago, according to the Tufts Center for the Study of Drug Development, Journal of the American Medical Association and Deloitte.

When asked about their biggest challenges, 49 percent of drug sponsor respondents in the FSP 2025 Trends Report survey listed the rising cost of clinical trials among their top five, while 39 percent cited challenges related to patient recruitment in clinical trials as a primary challenge. The need for both flexibility and efficiency is driving change across the industry. Sponsors must manage rising costs, more data, and shifting demands while keeping trials on track.

Mixed models that combine FSO and FSP services bring a new level of flexibility and efficiency, letting sponsors run high-quality trials across the globe without losing control. The proof is in the numbers: preference for mixed FSP/FSO models is increasing, with 33 percent of survey respondents preferring mixed FSP/FSO outsourcing to other models (up from 26 percent in the prior year), according to the report.

Exploring mixed FSP/FSO models for flexible support

A common application of mixed FSP/FSO models is when sponsors integrate FSP services into a new or existing FSO relationship, giving them greater oversight and the ability to apply their own standard operating procedures (SOPs) and systems while still accessing specialized expertise. These models work for all pharma and biotech company sizes and allow a tailored mix of internal and external resources to match the demands of any project, region, or therapeutic area, while maintaining control of critical or strategically important functions.

This approach also creates a safety net by creating multiple streams of support in the face of market volatility and strengthens budget and timeline security, particularly when FSP and FSO models are consolidated within one partner.

There are dozens of use cases when a mixed FSP/FSO model may be ideally suited to meet a drug sponsor's needs, including:

- **Addressing limited expertise/resources.** The mixed FSP/FSO model combines the scalability of FSP with the deep internal talent pool of FSO, giving sponsors immediate access to specialized expertise and flexible resourcing.

- **Maintaining knowledge and continuity.** The mixed FSP/FSO model can deliver consistency across studies and programs, regardless of the team on-site. For example, a dedicated medical writing team supporting all trials of a sponsor can ensure consistent terminology, quality delivery, and business continuity.

- **Expanding into new geographies.** The mixed FSP/FSO model often supplements FSO arrangements with FSP services, enabling efficient entry into new regions, access to local expertise, and broader patient recruitment without requiring full FSO or organizational infrastructure.

- **Scaling resources mid-trial.** The mixed FSP/FSO model lets sponsors quickly augment existing FSO capacity with targeted FSP resources, ensuring skilled personnel can be deployed rapidly to meet evolving trial demands and timelines.

- **Maintaining continuity during disruption.** The mixed FSP/FSO model enables sponsors to preserve staff expertise through approaches like rebadging, keeping trained personnel in place and ensuring trial stability despite business disruptions.

Opportunities for the future

The mixed FSP/FSO model also provides a smooth path for sponsors to shift from FSO to FSP engagements, maintaining continuity of operations while building internal expertise and scaling capabilities over time. By shifting some or all of a discrete clinical development service to an FSP model, this stepwise transition means they can keep programs running while increasing control over selected functions, boosting efficiency and training their internal teams for future independence.

Mixed FSP/FSO models will likely become even more popular as trial designs grow in complexity, new rules are introduced, and technology continues to change the drug development landscape. Sponsors who use these models can:

- Bring new treatments to market faster by avoiding common bottlenecks or slow-downs.

- Build programs that pivot easily based on trial results, regulatory changes, or global events.

- Maintain robust quality and compliance standards with the right expertise, in the right place, at the right time.

As clinical trials become more demanding, sponsors need innovative ways to stay flexible, efficient, and in control. Companies that use hybrid approaches will gain an edge – not only in meeting timelines, but in delivering better results for patients and more stable outcomes for their business. The future of clinical research demands agility, and hybrid outsourcing models are meeting the need head on.

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