CLINICAL RESEARCH NEWS Clinical Trials to the Clinic

Clinical Trials Evolve: Mixed FSP/FSO Models Add Agility and Expertise

Contributed Commentary by Les Enterline, Thermo Fisher Scientific

December 19, 2025 | For every day of delay in a clinical trial, sponsors lose $500,000 in prescription drug sales and incur $40,000 in direct clinical trial costs, according to the Tufts Center for the Study of Drug Development. These numbers show why speed and control matter more than ever, as drug development continues getting more complex and expensive. In the past 10 years, phase III clinical trial timelines are now 11% longer and the average research and development cost to develop a new drug has increased by 65%, rising from $1.3B in 2014 to $2.2B in $2024.

How sponsors choose to outsource clinical trial work shapes how fast, how well, and how affordably they reach the finish line.

Sponsors have leaned on two main outsourcing models for years. Full-service outsourcing (FSO) relies on a clinical research organization (CRO) to run everything for a clinical trial, from site selection and patient recruitment to data management and compliance. Functional service provider (FSP) models outsource certain functions, such as monitoring or data management. Now, more sponsors are mixing these models: mixed FSP/FSO models blend the strengths of both, meeting the rising demands of today's clinical research environment.

The Growing Use of Mixed Models

Picture FSO as hiring a general contractor to build your home. They manage plumbing, wiring, and painting. FSP lets you hire expert electricians or carpenters just for the jobs you need. Mixed FSP/FSO models blend both. You might keep the general contractor but bring in a kitchen specialist. Each approach has clear strengths. Smart sponsors use them to maximize their impact.

Mixed FSP/FSO models now make up about a quarter of clinical development work. Why are sponsors making this change? It comes down to flexibility, speed, and control. Mixed models let sponsors more efficiently scale teams up or down as clinical development needs grow or shrink, improving agility while maintaining oversight of critical trial functions.

With mixed FSP/FSO models, sponsors often bring in additional experts with deep skills in areas such as pharmacovigilance, data management or regulatory affairs, while still tapping into the broad skills of a full-service CRO. These additional resources often work inside the sponsor's own systems, follow their processes, and report to their leaders. This tight link helps sponsors act fast on new risks, adapt to rule changes, and ensure trials hit their timelines.

Enhancing Pharmacovigilance and Safety Monitoring

One common area where sponsors engage FSP or mixed model support is in pharmacovigilance (PV), due to the variable volume of cases and PV regulatory knowledge required to manage the process. While internal teams can, of course, be trained to handle this step, external partners bring added insight, expertise, and scalability to the task based on their broader capabilities and knowledge gained from working across sponsors, regions, and trials.

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Sponsors typically partner with an FSP for PV functions for two main reasons. First, it helps by freeing their internal PV teams to concentrate on core PV operations, strategic decision making, and risk mitigation. Second, it provides access to a best-in-class provider — delivering top PV talent, globally distributed expertise, and advanced systems. Being able to lean on outside support also makes it easy to scale up or down if needed, helping the program align with the case volume.

Mixed FSP/FSO models also bring vital regional PV regulatory expertise to clinical development operations when FSP partners are added to new or existing FSO engagements. Rules and guidance change often, and sponsors need to keep up. For example, some specialized PV regulatory teams track rule changes across over 100 countries — many in native language — to ensure sponsors remain in compliance. Adding the global reach and local know-how of an FSP partner helps sponsors avoid costly mistakes.

Strong communication channels between regulatory functions and PV teams are also critical. Experienced FSP partners set up regular updates, document workflows, and develop transparent action plans to act quickly when laws change.

Optimizing Clinical and Global Operations

Clinical operations — the heart of any trial — also benefit from mixed FSP/FSO models. These models create additional flexibility to match resources to peak periods, cover hard-to-reach regions, and maintain continuity during disruptions. When a trial needs to move into new countries, sponsors often face slow site startup, unfamiliar local rules, and trouble finding patients. Mixed FSP/FSO models let sponsors add specialized FSP expertise to their existing FSO setup, bringing in local experts to solve these problems.

Adding FSP resources to FSO engagements through remote-based regional hubs is another way mixed FSP/FSO models create additional speed and efficiency. This model gives sponsors access to highly skilled professionals without the geographic restrictions associated with conventional brick-and-mortar office setups concentrated in select major cities.

FSP resources provided through remote-based regional hubs propel projects forward by helping accelerate recruitment and onboarding, enhance internal capabilities with additional on-the-ground support, increase productivity with the ability to create continuous workflows across global time zones, and allow sponsors to quickly expand into non-footprint countries. The result is faster site activation, better patient diversity, and stronger data, since local teams more closely connect with sites and communities. The additional flexibility provided by mixed FSP/FSO models allows drug developers to scale the resources, support, and expertise to match shifting workloads and new or unexpected demands in global markets.

Evolving to Stay on Track

Mixed FSP/FSO models are providing sponsors with additional control, speed, and efficiency to optimize their clinical development operations. Besides extending internal expertise, mixed FSP/FSO models offer an additional level of flexibility to create bespoke clinical development solutions that complement each sponsor’s existing capabilities and needs. When every day and dollar count, this approach is not just smart. It is vital.

The goal for clinical research has remained the same for decades: deliver new treatments to patients quickly, safely, and effectively. But clinical trial sponsors now have more tools at their disposal to unlock faster and more efficient outsourcing strategies to meet their timelines. The data, the market, and current clinical development results all point the same way: mixed FSP/FSO models help ensure the next medical breakthrough stays on track.

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