

Measuring What Matters: *Designing a Future-Fit FSP Model for Modern Drug Development*

The Functional Service Provider model has grown from a tactical staffing mechanism into a strategic outsourcing framework that underpins modern clinical development. Yet, despite its evolution, the way many organisations measure FSP performance has not kept pace. For too long, success has been defined by simple inputs: how many people are on the team, how quickly they can be onboard and what their blended rates are.

These metrics were adequate when clinical pipelines were smaller, regulatory requirements were less complex and digital tools played only a supporting role. Today, however, clinical trials are more data-intensive, decentralised and globally distributed than ever before.^{1,2} The stakes are higher, timelines are tighter and R&D budgets face unprecedented scrutiny.

According to the Tufts Centre for the Study of Drug Development, the average cost to develop and gain approval for a new prescription medicine now exceeds \$2.5 million, while development timelines frequently exceed ten years.^{3,4} At the same time, the cost of drug R&D has increased,⁵ putting sustained pressure on sponsors to extract greater value from every dollar invested. In this environment, outsourcing models can no longer be judged merely by capacity or headcount, they must deliver measurable performance, tangible efficiency gains and demonstrable value.

The Evolution of FSP in a Changing Outsourcing Landscape

Functional outsourcing has grown steadily over the past two decades. Industry analysis estimates that more than 50% of clinical development activities are now outsourced, with functional outsourcing representing one of the fastest-growing segments.⁶ Historically, full-service models

dominated, but sponsors are increasingly seeking hybrid and functional arrangements that preserve strategic oversight while leveraging specialised external capabilities.

Surveys of biopharma sponsors show that approximately 35% of companies have increased FSP usage in the last two years, reflecting a clear trend toward functional delivery models.⁷ These arrangements provide three clear advantages:

- Functional depth in specialised disciplines such as biostatistics and programming.
- Operational continuity across complex portfolios.
- Cost transparency at a functional level.

But, with the industry entering the next phase of maturity FSP models must evolve from headcount management to performance-led delivery.

The Structural Limits of a Headcount-Driven Model

Traditional FSP models scale linearly. More work requires more people. Portfolio peaks trigger resource requests. Risk mitigation often results in increasing seniority levels unnecessarily.

Over time, this creates inefficiencies:

- Senior statisticians and programmers performing repeatable production tasks.
- Rising cost structures without proportional productivity gains.
- Underutilisation of automation.
- Delivery risk accumulating quietly in complex team structures.

Linear scaling is misaligned with modern drug development, where portfolio volatility is high and submission timelines are critical. True efficiency comes not from more bodies but from smarter allocation of resources and systems.

Redefining What We Measure

A future-fit FSP model should be guided by three core questions:

- Are we delivering more with less effort?
- Is work consistently performed at the right level of expertise?
- Is automation replacing human effort rather than merely supporting it?

These questions shift the focus from staffing to system performance.

Speed: End-to-End Cycle Time

The meaningful metric is not time to hire. It is cycle time per deliverable. Sponsors should track:

- End-to-end cycle time for SDTM, ADaM and TFL outputs
- Cycle time reduction attributable to automation
- Time to scale functional capacity up or down

Even modest improvements in cycle time can have a meaningful impact on regulatory submissions and time-to-market advantage resulting in cost efficiency gains.



Quality: Right-First-Time Delivery

Project level on-time metrics are insufficient. They only flag issues after timelines are at risk. Next-generation FSP requires near real-time Right-First-Time measurements at the task and resource level. Early detection of rework trends enables proactive intervention and risk mitigation.

Cost: Evaluate Per Deliverable

Cost should be evaluated per deliverable, not per resource. Resource mix ratios are critical. The goal is not simply geographic arbitrage, but task alignment.

A meaningful KPI is a percentage of work delivered at the intended skill ratio (junior, senior, principal). This ensures senior expertise is reserved for high-value decision-making, while production work is delivered at appropriate cost levels.

THE THREE PILLARS OF A NEXT-GENERATION FSP MODEL

Pillar One: Resource Optimisation

Resource optimisation requires deliberate task allocation. Repeatable production work should not sit with high-cost senior profiles. Instead, tasks should be assigned based on:

- Task complexity
- Required expertise
- Geographic cost structure

For example:

- SDTM and ADaM production can be delivered by junior resources in lower-cost regions, supported by automation.
- Validation can sit at senior level in mid-cost regions.
- Strategic oversight and final accountability remain with principal leads.

The result is fewer total resources, stronger ownership clarity and higher-value use of senior expertise.

Pillar Two: Automation as a Structural Level

The second key shift is making automation a structural part of the operating model. Repeatable activities such as SDTM generation, TFL production, SAP shell development and standard QC workflows should not scale through people alone, they should scale through technology.

Automation does not eliminate human oversight or accountability. Instead, it removes friction from repeatable processes, allowing teams to focus on higher-value work that requires judgment, interpretation and decision-making. When embedded thoughtfully, automation accelerates delivery, improves consistency and enables faster timelines, ultimately supporting submission readiness and strategic objectives.

Pillar Three: Flexibility Through Capacity Design

Portfolio demand fluctuates. Submission peaks, remediation programs and accelerated approvals create variable workload.

A future-fit FSP model designs:

- A steady-state core team
- Flexible surge capacity layered above it

This capacity-as-a-service approach avoids permanent headcount inflation while maintaining responsiveness.

Mobilising Outcome-Based FSP Partnerships

Designing a next-generation FSP model is only half the journey. Mobilising it across complex sponsor environments globally requires structured execution.

FSP mobilisation should be treated as an operating model transformation, not a staffing exercise. This transformation includes five key stages:

1. Establish baseline performance – cycle times, rework rates and resource mix alignment.
2. Co-design work allocation frameworks – task complexity, accountability and automation opportunities defined upfront.
3. Embed automation from day one – standardised tools, reusable code frameworks and automated validation workflows.
4. Implement real-time dashboards – task-level visibility drives proactive risk mitigation.
5. Scale flexibly – surge capacity adjusts with portfolio demand without destabilising the core team.

The result is a delivery ecosystem engineered for measurable, sustainable performance, not simply capacity.

Designing for What Matters

When resource optimisation, embedded automation and engineered flexibility align to outcome-based metrics, sponsors unlock durable advantages:

- Speed – reduced cycle times.
- Quality – protected senior oversight and reduced rework.
- Flexibility – capacity responsive to portfolio needs.
- Cost – structural efficiency rather than reactive reduction.

The future of FSP is not about headcount expansion. It is about intelligent ecosystem design that not only meets today's needs but is designed to evolve with the demands of the future.

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