Enhancing Clinical Trial Flexibility

Drug development costs continue to escalate, which incentivizes sponsors to find less expensive approaches to develop their drug assets. During 2022, the top fifteen pharmaceutical companies invested a record $138 billion in research and development, 43% over 2017 spending.[1] One of the ways to trim costs and be more efficient is to outsource some areas of drug development. When outsourcing, sponsors have found it acceptable to utilize contract research organizations (CROs) and functional service provider (FSP) models. In recent years, many companies have realized the benefits that narrower, functionally-specific FSP models provide, which has made FSP increasingly relevant.[2] Now FSP models provide increased operational and resourcing flexibility and different pricing plans in comparison to traditional full-service CRO offerings.

The history of FSPs

In the mid-1900s, sponsors started to employ some of the first outsourcing services. By the 1980s, a handful of CROs were in business. These days, there are more than a thousand outsourcing companies available.[3] Nearly 25 years ago, standalone FSPs were formed to support the sponsors' needs for an expanding (or contracting) workforce.[4] Because of the FSP model's flexibility and scalability, FSPs are no longer seen as only extensions for staffing. Over the years sponsors have reduced internal capabilities and embraced the functional services model, enabling them to secure pliant resources in functional offerings.

Through this period different FSP models have emerged to address drug development in all areas of clinical trials, specifically those performed in-house and for Phases I, II, and III.[5]

The need for the hybrid approaches that FSP offers, as well as more cost-efficient, adaptable solutions for drug development, has supported the growth of FSP offerings. In 2018, "market sizing estimates put the contract clinical service industry at over $30 billion."[6]

Biotechnology companies and large pharma favor multiple models to meet their outsourcing needs. However, biotech companies feel underserved by the inflexibility of the FSP models large companies provide, especially in functional areas such as medical writing, biostatistics, data management, safety, and clinical monitoring. Even though the industry's innovation and growth are driven by them, biotechs "quite commonly believe that they are not fully prioritized in terms of CRO team experience and expertise, with members lacking the ability to advise them strategically. They also report high turnover of key personnel, such as clinical-research associates."[7]

Sponsors, looking to augment or supplement their internal teams, most often do not stay with one specific outsourcing model. In fact, some sponsors find more flexibility in using three or more models simultaneously[8] and engaging resources with a breadth and depth of expertise not available in-house. FSP delivers capabilities across a broad base, including subject matter experts in the functional areas already noted as being underserved. Sponsors often seek "a more collaborative approach to the oversight process rather than just focusing on more tactical and executional approaches to issue management and reporting."[9]

CASE STUDY

Catalyst Flex initially provided three data managers then scaled to add multiple roles across clinical programming, technical writing, medical coding, lab support, and electronic data capture (EDC) programming. Without Catalyst Flex's flexibility and listening, the sponsor would not have had the successful programming efforts and deliveries needed for various milestones and deliverables.

Advantages of working with a flexible FSP model

It is no secret that expertise in functional areas accelerates drug development delivery. Plans for outsourcing will include functional areas that augment a sponsor's internal technology, resources, and people. With a tailored-for-need FSP model, cost efficiencies arise from aligning experienced staff with a deep understanding of managing costs and enabling them to successfully plan work.

We have watched as the FSP model has gained acceptance, moving from supplying a full-time employee to a more deliberate partner with the sponsor. Today's FSP offerings should lead with a solutions-oriented approach that supplies the right people, processes, and technology with approaches that are adjustable and scalable, and are designed to flex as needs change.

Providers must scale to deliver to the sponsor one or two individual resources, a single function within a trial, or fully outsource a dedicated team across multiple programs. The solution should incorporate the sponsor's processes, the provider's processes, or a blend of the two. A provider is more than hiring and working with a vendor. A sponsor should feel a true partnership with an adaptable provider willing to help achieve high-quality, cost-effective results.

> *Large and mid-size pharmaceutical organizations are undergoing clinical outsourcing paradigm shifts decreasing their dependencies on FSO and focusing on best-in-class portfolio solutions. FSP organizations are gaining market share given their abilities to create bespoke, flexible solutions across people, processes, and technology.*
> **Samir Shah, Industry Expert**

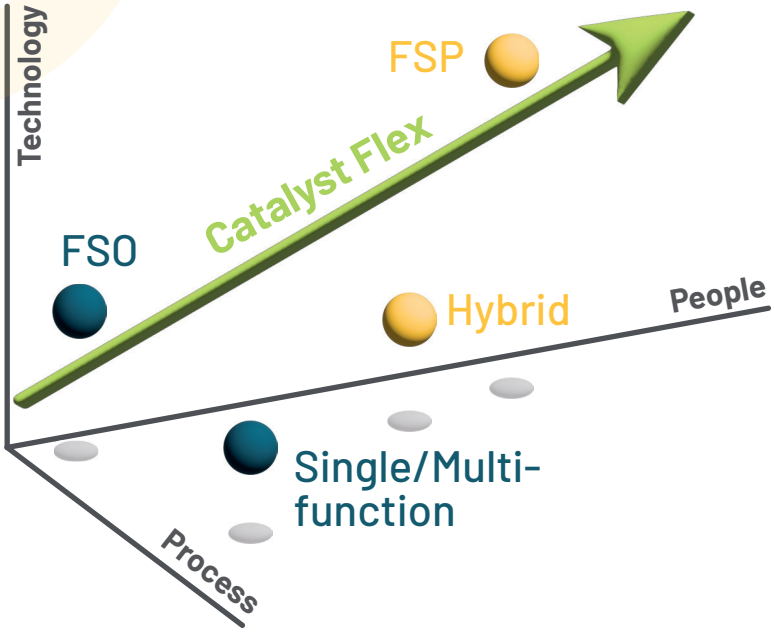
CASE STUDY

Catalyst Flex assisted a small biotech with functional support for a Phase III rare disease study. Although a contract existed between the biotech and a CRO, the study timelines and budget had slipped. The biotech hired Catalyst Flex to reverse that trend and ultimately saved the biotech ~$1 million.

In addition to working with a flexible FSP model to optimize resources, leveraging a suite of technology offerings allows for bespoke functional solutions or a sponsor to use its own tools. FSP offers solutions for sponsors in safety and medical writing, biometrics, or clinical resources. Additionally, FSP can ensure short- or long-term, part- or full-time resources. These can be contract individuals or teams. While many companies providing FSP show a menu of offerings, these offerings can create inflexibility. While a sponsor may know it needs a certain service, such as data management, a menu of offerings often does not allow for the customization of such services.

Instead, a sponsor should engage an FSP with a hybrid approach. Such providers listen to and learn from sponsors to then offer unique, custom solutions that solve the sponsors' challenges. Whether it is expertise in multiple therapeutic areas or multiple functions, the provider should offer deep knowledge that ensures successful delivery. FSP leaders with decades of experience within functional outsourcing help sponsors take advantage of their extensive knowledge to offer a tailored solution. Such an offering may include technology integration, scalability and resource allocation, and cross-functional collaboration with subject matter experts.

Landscape of FSP models: How different models work today



Through a model such as the one suggested above, a provider can assess and respond to a sponsor's needs, then help to design and deliver better clinical trials. By developing a hybrid method and new ways of working, FSP celebrates a diversity of ideas and thrives on new challenges.

The sponsor should expect an FSP model adapted and created as a customized, fit-for-purpose offering, which results in cost and time savings. This ensures that FSP designs hybrid solutions across functional and full-service capabilities, leveraging its partnerships.

As needs for multiple outsourcing models continued expanding over the past three decades, there has been a growing need to define these models and align on a taxonomy. One such effort offers the following table to differentiate the permutations and combinations of FSO and FSP-like services. This framework and taxonomy provide the basis for the landscape Catalyst Flex uses to illustrate a different approach.

	Managed Services Umbrella		Mixed Models	Functional Continuum Umbrella		Internal Pharma Managed
Model	Full Service	Single/Multi-Service	Blended	Embedded	FSP	In-House
Also Called	FSO, CRO, Programmatic Outsourcing, End-to-end	Standalone/ Modular services, Largely outsourced	Hybrid, Enhanced	FSP 2.0	Functional Service Provider	Insourced, staffing
Scope of Vendor Services	All activites/ functions (core & non-core)	Single or multiple services/ functions	Full spectrum of activities within a given function that may include elements of different models	Dedicated activities leveraging wider Vendor value	Dedicated activities delivered at the Functional Level; Could be multiple functions	None
Application/ Methodology	Planning and strategic execution predominantly manged by vendor	Outsourcing of single or multiple service lines for program/ portfolio	Customized and bespoke to fit sponsor-specific needs; Designed to optimize functional capacity management	Ability to use Functional Management with Service Level Agreement; Vendor takes additional responsibility. Aims to optimize capacity	Strategic capacity management utilizing teams of dedicated resources for FTE model, or core group, trained pool of non-dedicated resources for unitized delivery	All planning and execution managed by pharma company
Systems & Processes	Predominantly vendor	Predominantly vendor	Vendor or Sponsor	Predominantly Sponsor	Sponsor	Sponsor
Accountability for Project or Functional Timelines	Predominately vendor	Predominately vendor for accountable services only	Increasing milestone/ performance-based pricing vs. more time & materials (FTE/hourly)	Predominantly Sponsor	Sponsor	Sponsor

Increasing milestone/deliverable and/or performance-based pricing vs. more time & materials (FTE/hourly)

Sponsor-provided Infrastructure increases. Responsibility and accountability for delivery remains with Sponsor

Vendor project delivery and accountability increases along with transfer of sponsor responsibilities

[10] Note from Getz, K., Shah, S., Luithle, J., Travers, M. (2022) Redefining CRO Sourcing Model Terminology to Optimize Outsourcing Strategies. Applied Clinical Trials. Copyright 2022, MJH Life Sciences.

Full Service Outsourcing (FSO)

- Outsourced on project and/or program basis
- Leverages Contract Research Organization (CRO) systems processes and access to therapeutic expertise
- Can drive efficiency and quality by allowing CRO to operate in its own environment

Functional Service Provider (FSP)

- Embedded into sponsor's infrastructure
- Leverages sponsor's systems and processes
- Allows sponsor to retain portfolio control and more direct engagment with investigative sites

How to select an FSP model and partner for your projects

When setting out to choose the FSP model and right partner for a project, take time to assess your requirements and objectives. Explore your in-house team's technology readiness to determine where broad integration strategies may be applied with a FSP partner. In addition to the services offered, assess engagement from the FSP organization and its responsiveness, expertise, and flexibility. By selecting the appropriate functional service provider, you will create a partnership providing consistency with a single operating platform—without having to bolt on different solutions—while reducing the burden on internal teams and investigator sites. From a site standpoint, this enables a strong foundation for engagement throughout the project and beyond.

Clinical trials are complex and require specific expertise. Consider what will happen when everything goes well? Or if a trial has a challenge? When planning your requirements, engage with a trusted partner to build the right team and the right relationship for your needs.

It is essential to find a partner that will be there for when everything works well or is challenging.

Whether your research requires technology integration, sponsor-provided or provider processes to address any scalability or resource allocation needs, or other cross-functional collaboration with experts, an FSP should support listening, learning, and flexibility as core values to help drive unique solutions and success.

With the growing number of clinical trials, functional service providers will continue to keep pace, offering services to augment in-house functions. Working with a flexible FSP model will increase savings while accelerating drug development.

CASE STUDY

When a development-stage pharmaceutical company sought a partner organization that could manage a new study with an ambitious time of around four months, the partnership between Catalyst Flex and the sponsor resulted in successful study completion ahead of planned timelines with high-level results. The sponsor chose an experienced partner to ensure the desired study endpoints were met.

Catalyst Flex, a brand of Catalyst Clinical Research, provides global functional services delivered by experts in clinical operations, data management, biostatistics and programming, safety and pharmacovigilance, and medical writing for the biopharmaceutical and biotechnology industries. As a functional service provider, Catalyst Flex supplies people, process, and technology solutions designed to meet each client's unique needs. Catalyst Flex's flexible service model comes from our long history of listening to customers, devising customer-centric solutions, and helping customers advance their work by leveraging expert teams and innovative technologies.

Catalyst is a portfolio company of QHP Capital, a leading healthcare and life sciences investment firm.

catalystflex.com

Authors

Craig McIlloney, MSC, BSc Hons, Senior Vice President, Catalyst Flex

Craig brings 25 years of experience in drug development with small and large CROs to his role with Catalyst. As Senior Vice President of Catalyst Flex, Craig is responsible for the global execution of functional services across multiple therapeutic areas. In his previous roles, Craig has overseen global operations across multiple functions including but not limited to data management, biostatistics, statistical programming, medical writing, quality, analytics, systems, and communications. This has included global expansion across multiple regions and his leadership experience spans activities across various delivery models, including FSP, full-service, and hybrid models. He earned a B.S. (Hons) degree in statistics from the University of Glasgow, U.K., and an M.S. in applied statistics from Napier University, Edinburgh, U.K. He is a chartered statistician (Cstat) with the Royal Statistical Society and was previously a director of the Statisticians in the Pharmaceutical Industry (PSI).

Svetlana Kolchinsky, Vice President, Catalyst Flex

Svetlana brings to Catalyst Flex over 15 years of experience in clinical project management and leadership covering all facets of clinical development. Her professional journey began in 2000 at an NIH/NINDS research group. After scientific research, in 2003, Svetlana transitioned into clinical research at Immune Tolerance Network. In 2008, with a newly acquired passion for clinical research, she joined BioTelemetry (formerly Cardiocore), a cardiac safety core lab. While at BioTelemetry, Svetlana led project management, biometrics, and customer support functions. Using her leadership experience and strong project management skills, Svetlana joined Nanobiotix with a single goal of ground-up creation of an in-house project management operation for an ongoing portfolio of projects in the European Union and the U.S. For the last ten years, Svetlana has been a part of the clinical research industry. She has been privileged to work with some of the brightest minds in the biotech and pharma industries, helping them bring life-changing treatments and products to patients. In 2020, she joined Catalyst Clinical Research and has been successfully building effective clinical research teams and leading Catalyst Flex clinical development operations.

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