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# Redefining CRO Sourcing Model Terminology to Optimize Outsourcing Strategies

Differentiating FSO and FSP approaches can better align definitions of models for CROs and sponsors.



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## Introduction

The market for contract clinical service delivery models has continued to evolve and grow in step with a maturing global drug development enterprise. Over the course of more than three decades, reliance on outsourcing has intensified, as sponsor companies seek more capacity and scale, scientific and executional expertise, cost containment and operating efficiency. Indeed, spending by biopharmaceutical companies on contract service delivery models is growing rapidly at 6-8% annually, far faster than the rate of spending by sponsor companies on internal R&D operations and infrastructure.<sup>1,2</sup>

Underlying landscape trends driving growth in demand include the rising prevalence of small companies with highly limited clinical research capacity and talent; leaner sponsor company operating models; and ongoing biopharmaceutical company desire to continuously assess which competencies offer strategic advantages that should be retained in-house or handled by external collaborators.



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## Sourcing models—defined in the past

Twenty years ago, “full-service outsourcing (FSO)” and “Functional Service Provider (FSP)” were distinct models and biopharmaceutical companies tended to gravitate to one or the other.

Over time however, the distinction between FSO and FSP has become harder to define. Today, sponsor companies use a variety of contract service delivery models simultaneously to support their studies, mixing and matching a wide variety of outsourcing approaches that vary from study to study.

In part a result of the variety and combination of approaches used, at this time the terms FSO and FSP are frequently misunderstood not only between

companies but also within companies, across functions and therapeutic areas. As a case in point—here are definitions of FSOs in the literature:

- “A company hired by another company or research center to take over certain parts of running a clinical trial. The company may design, manage, and monitor the trial, and analyze the results.”<sup>3</sup>
- A CRO that “provides planning and execution of a clinical study, including oversight and accountability for key milestone delivery, from our centralized project management team.”<sup>4</sup>
- “A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor’s trial-related duties and functions.”<sup>5</sup>

‘Full Service,’ for example, has largely become a catch-all phrase that has limited meaning or relevance. Many sponsors characterize their outsourcing approach as Full-Service when, in fact, their approach falls somewhere between FSO and FSP.

There are a number of reasons why there is so much confusion today. Many sponsor companies are simply too large and too fragmented to consistently adhere to a single outsourcing model. Clinical projects have become so complex that they require support from a larger and more diverse group of providers.<sup>6</sup> And many large sponsor companies that have formed outsourcing relationships still have significant in-house development resources creating internal competition with comparable external resources.

Legacy activity underway when new partnerships form also contributes to the problem. Clinical teams typically have established their own relationships with select service providers and resist handing-over



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Full-Service Outsourcing– FSO	Functional Service Provider – FSP
<ul style="list-style-type: none"> <li>• Outsourced on project and / or program basis</li> </ul>	<ul style="list-style-type: none"> <li>• Embedded into sponsor’s infrastructure</li> </ul>
<ul style="list-style-type: none"> <li>• Leverages CRO systems &amp; processes and access to therapeutic expertise</li> </ul>	<ul style="list-style-type: none"> <li>• Leverages sponsor’s system &amp; processes</li> </ul>
<ul style="list-style-type: none"> <li>• Can drive efficiency and quality by allowing CRO to operate in its own environment</li> </ul>	<ul style="list-style-type: none"> <li>• Allows sponsor to retain portfolio control and more direct engagement with investigative sites.</li> </ul>

**TABLE 1.** A New Framework and Taxonomy Characterizing Sourcing Models in Use

	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 Services	Stand-Alone Services / Modular Services, Largely-Outsourced	Hybrid, Enhanced	FSP 2.0	Functional Service Provider	Inourced, Staffing
Scope of Vendor Services	All activities / functions (core and non-core)	Single or multiple services/functions	Full spectrum of activities within a given function that may include elements of different models	Dedicated activities / functions leveraging wider Vendor value	Dedicated activities delivered at the Functional Level; Could be multiple functions	None
Application / Methodology	Planning and strategic execution predominantly managed by Vendor	Outsourcing of single or multiple service lines for a defined 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 on additional levels of responsibility. Designed to optimize functional capacity management	Strategic capacity management utilizing teams of dedicated resources for FTE model, or core group with trained pool of non-dedicated resources for unitized service delivery	All planning and execution managed by Pharma company; May include supplemental use of contingent labor for staff augmentation
Systems & Processes	Predominantly Vendor	Predominantly Vendor	Vendor or Sponsor	Predominantly Sponsor	Sponsor	Sponsor
Accountability for Project or Functional Timelines and Deliverables	Predominately Vendor, Sponsor influence and approach varies	Predominately Vendor for accountable services only	Increasing milestone/ deliverable and/or 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

existing projects to new collaborators. Companies going through mergers and acquisitions, in particular, are often forced to permit inconsistent practices across organizational functions to ensure that legacy projects are completed as new approaches are introduced.

Another reason is the turnover of key senior staff advocating for, overseeing, and implementing a given sourcing strategy. Outsourcing strategies that have not sufficiently been adopted are prone to fall apart when new executives, who might have different ideas about sourcing models, take over.

As a result, in practice, current outsourcing models being used reflect a wide spectrum of permutations and combinations.

## A compelling need for new terminology

Lack of distinction, poor understanding, and misuse of the terms FSO and FSP ultimately fail to provide sponsor companies with meaningful and actionable insight to inform strategic decision-making and continuous improvement. Although biopharmaceutical companies collect a vast amount of operating data today to inform, predict and ultimately optimize clinical trial performance, without a clear understanding of differentiated outsourcing models used, this data offers insufficient insight overall and by function into the contribution and comparative value of a given model or combination of models.

Moreover, although the original definitions of

**TABLE 2.** Illustrative Examples of Sourcing Model Combinations

Company or Study	Start-Up	Clinical Monitoring	Data Management	Stats/Programming	Medical Writing
A	Multi-Service	Multi-Service	FSP	FSP	FSP
B	Embedded	FSP	Single Service	Internal Pharma Managed	Single Service
C	Internal Pharma Managed	FSP	Single Service	Single Service	Single Service
D	Multi-Service	Multi-Service	Multi-Service	Internal Pharma Managed	Internal Pharma Managed
E	FSP	Embedded	FSP	Single Service	Single Service
F	Embedded	Embedded	Multi-Service	Multi-Service	Multi-Service
G	Multi-Service	Multi-Service	Multi-Service	Internal Pharma Managed	Multi-Service
H	Internal Pharma Managed	Multi-Service	Multi-Service	FSP	FSP

FSP and FSO outsourcing models have not adapted during the past two decades, sponsor company operating models have continued to evolve. As such, it is essential that we update outsourcing terminology to accurately describe the work actually being performed. This can best be achieved through gathering broad industry input and developing consensus definitions that can be easily applied to outsourcing strategies and decision-making.

We propose that the underlying principle now differentiating the permutations and combinations of FSO and FSP-like services is the employment of the CRO’s infrastructure, processes and potentially the CRO’s standard operating procedures (SOPs) for clinical trial conduct. During the past ten years, sponsor companies attempted to differentiate their outsourcing practices according to the type of contracting services (e.g., unit-based, deliverables, outcomes versus FTE) and/or the level of accountability assigned to the CRO. The reality is that sourcing models are adjusted and adapted across multiple service lines as organizations continue to evolve.

Based on extensive input from ICON’s pharmaceutical company Partners of Choice community and in-depth discussions with individual sponsor companies, the following framework (see Table 1 below) has been developed to characterize the variety of sourcing models used across three primary parameters: (1) outsourcing orientation; (2)

infrastructure support; and (3) accountability and contracting structure.

Given their size, configuration, portfolio, and core competencies, many of the mid- and large biopharmaceutical companies leverage “mixed models” and combinations of sourcing models at the clinical trial level. Other sponsor companies, for example, have different sourcing approaches depending on the strategic value of the asset in development (e.g., registration/pivot in one model and late-stage/post-approval in another) and the therapeutic area. Table 2 below presents, for illustrative purposes, an application of our proposed sourcing model framework to better characterize the variation in approaches that sponsor companies are using to leverage contracted clinical services.

### Concluding thoughts

We invite comments and input into this proposed new taxonomy and framework. It is our hope that this framework will be discussed, refined, and improved. Versions of this framework will ultimately serve as a more relevant and useful approach to identifying models—and combinations of models—associated with higher levels of performance, efficiency, and quality.

With a lack of differentiation between FSO and FSP approaches today, it is critical for both CROs and sponsor companies to align on definitions of

sourcing models in use. Universal definitions will ensure common understanding between partners and across the industry with respect to roles, responsibilities, and accountabilities. Consistency in the descriptions we use to characterize “how we work” is also critical for establishing industry-wide recognition and acceptance of benchmarks that enable more meaningful and reasonable comparisons in the effectiveness of one or a combination of sourcing model(s) over others across the life of a development project. All of which will ultimately lead to higher quality work and improved outcomes for patients.

ICON is currently engaging with the Tufts Center for the Study of Drug Development (Tufts CSDD)—with input and in collaboration with ICON’s biopharmaceutical company Partners of Choice (PoC)—to conduct a primary research study comparing clinical trial performance outcomes through the implementation of more meaningfully defined and relevant sourcing model strategies. 🍌

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