

Industry Trends and a Shift to FSP Outsourcing

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FSP OUTSOURCING
TRENDS REPORT

February 2022

Industry Trends Drive Increase in Functional Outsourcing

Opening Statement: The industry continues to need to do more with less, which has driven the evolution of different resourcing strategies. Companies have complex and changing portfolios, requiring agility to get medicines to patients faster – without sacrificing quality. This has been especially important during the pandemic, as companies have had to balance new ways of working and focusing on novel areas of research. This has increased the need for more flexible approaches due to an enhanced emphasis on remote capabilities, challenging sponsors to identify outsourcing partners who can provide therapeutic, technological and/or geographical expertise where they may be lacking or are simply unable to hire.

We all understand full-service outsourcing, but for the purposes of this report we will be discussing outsourcing by specific functions and/or working within clients' standard operating procedures and systems – known as a functional service partnership or FSP – and how recent industry challenges have led to a shift in outsourcing from a split of 72% FSO / 28% FSP in 2018 to a more even mix over the last three years with projected ratio in 2021 at 59% FSO / 41% FSP.

List of terms used throughout the report

FSO – Full-service outsourcing

FSP – Functional service partnership

CRA – Clinical research associate

CRO – Clinical research organization

Key Industry Challenges

Industry Challenge # 1 – Speed to Market

With pressure to meet demand to get to market, sponsors are challenged with getting sites and studies up and running faster than ever in the current landscape where routine travel in some geographies remains challenging and patient access to treatment for a number of indications has lagged since many studies were disrupted and delayed during the pandemic. Nearly 60% of respondents in a recent PPD® Digital survey reported that a patient's ability to visit an investigative site was the most impacted aspect of their ongoing clinical trials during COVID-19.¹ To better ensure continuity of care, the focus on remote technologies and digital solutions has grown dramatically with more than 50% of site survey respondents confirming that they have implemented remote monitoring visits, reduced site visits and moved from paper to digital versions of patient clinical outcome assessments.

In addition, to bridge the gap in speed to market, there has been an increase in the number of sponsors specifically looking to outsource **study startup as a stand-alone function**. Sponsors interested in this solution appear to be addressing the issue in three key ways:

- Rapid startup to reduce the overall time (and cost) of conducting a study
- Leveraging a CRO or strategic partner to provide resources in countries where the sponsor may not have representation or capacity
- Centralizing the process globally to ensure standardization and increased efficiencies

Industry Challenge # 2 – Talent Shortage

With the demand for clinical research professionals at an all-time high, sponsors and CROs are competing for the same talent, creating a market-driven landscape and increasing turnover ratios. This lucrative environment for candidates often provides opportunities to entertain multiple offers at once. The results for CROs and sponsors include increasing salaries coupled with compelling compensation packages.

As an example, within the CRA space in North America, the demand for professionals in that role is more than double the capacity available.² This has led to an average increase in salaries of approximately 15% over the past six months.³

With demand exceeding capacity, sponsors are looking to CROs to provide resources where they are unable to hire in time to meet their needs. This has resulted not only in an increased volume of requests, but also in a shift in the level of talent being requested. As summarized by Les Enterline, senior vice president of PPD® FSP, "One area where we have seen an interesting shift from historical requests is both with large pharma and biotechs requesting more senior and experienced individuals. COVID-19 has accelerated the need for clients to have rapid access to additional highly trained professionals to support their pipelines in what already was a highly competitive market. Clients who used to request one or two senior professionals now are asking for 20, 30 or even as many as 90 FTEs across multiple functions. They simply cannot find and hire staff fast enough or they do not want to assume the risk of increasing internal headcount."

¹PPD Digital survey **Decentralized Clinical Trials Survey Report** | PPD Inc

²This is a PPD Metric

³This is a PPD Metric

Key Industry Challenges

One remedy to this talent shortage includes partnering with a CRO that has an enterprise-connected, singular talent pool – even for functional service partnerships – as opposed to one that relies on an FSP-only resource pool. Leveraging a CRO’s shared resource pool and global infrastructure benefits sponsors with shared knowledge and faster, easier access to even better talent across a multitude of functions.

Industry Challenge # 3 – Becoming the “Sponsor of Choice”

With available resources at a premium and the increased focus on speed, investigative sites must prioritize sponsors and studies more than ever. This has resulted in sponsors vying for priority placement with investigators to run their trials. With an emphasis on making sites “happy,” we look at some of the primary pain points for sites such as CRA turnover, timely payment and prompt responses to protocol questions topping the list. An Industry Standard Research (ISR) focus group concluded that “high monitor turnover leads to unfruitful relationships between sites and CRAs and increased workload for the site staff” (*Risk-Based Monitoring: Improving the Clinical Trial Site Experience, May 2017*).

With so much riding on successful relationships, the CRA often becomes the face of the sponsor. Sponsors want to be able to prioritize sites, influence CRA behaviors and ensure an overall positive partnership with their key investigators. As part of this solution, an FSP has become a popular option for sponsors who want to assign a monitoring team that can align to their specific systems and processes without carrying the long-term cost of hiring and managing the team.

R&D: THE YEAR THAT’S OUTPACING A DECADE

At unprecedented speed and scale, virtually every sector in drug development is shattering records in the quest to bring therapies to market.

For the past decade, our industry has witnessed a steady influx of activity in the R&D pipeline. This increase in R&D activity has had a ripple effect on the number of registered clinical trials.

Drugs in the pipeline



CAGR* of **7%** for pipeline drugs.

*CAGR=compound annual growth rate

Source: Pharma R&D Annual Review 2021. Informa Pharmaprojects®, January 2021

Registered clinical trials

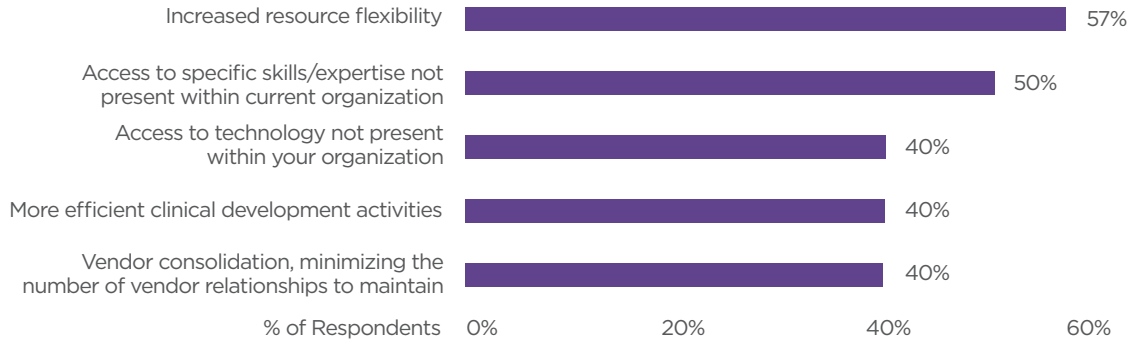
3x

Registered clinical trials tripled in the last decade from **100,208** at the beginning of 2011 to **362,521** at the beginning of 2021.

Source: ClinicalTrials.gov. Accessed on 10/5/2021. <https://clinicaltrials.gov/ct2/resources/trends#RegisteredStudiesOverTime>

Trends in Outsourcing

Based on a report done by Industry Standard Research, the top 3 ranked benefits of working in an FSP model included:



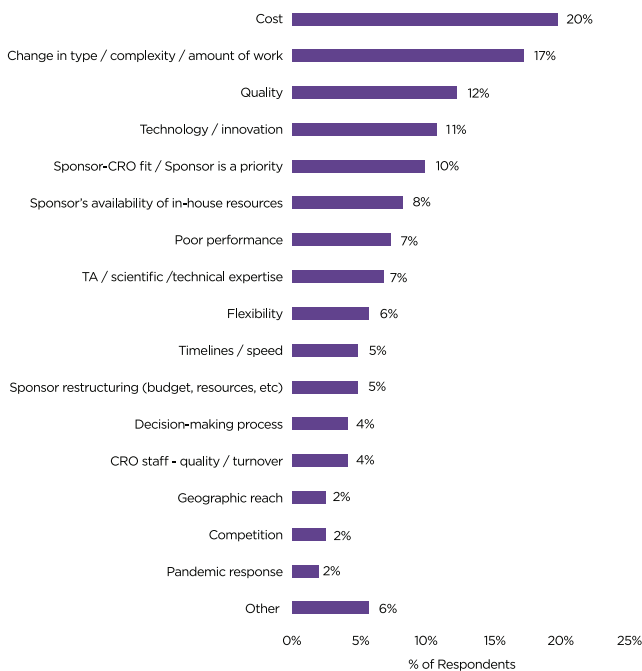
Impact of COVID-19

The COVID-19 pandemic has created an uptick in FSP utilization, predominantly by three company archetypes:

- Companies starting trials of new COVID-19 diagnostics, vaccines or treatments are using the FSP model to scale up without impacting other ongoing studies
- Companies that need to bolster a specific type of expertise or fill a geographic gap are using FSP in a very targeted fashion
- Companies that have accelerated their use and acceptance of remote monitoring, eCOA, etc.

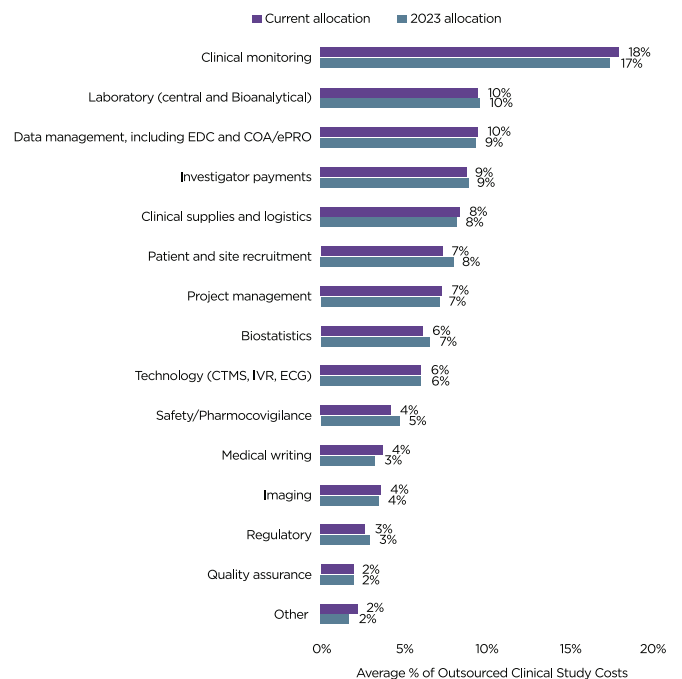
Industry Outlook and Drivers

Top reasons for selecting changing an outsourcing model



Source: Industry Standard Research, 2021

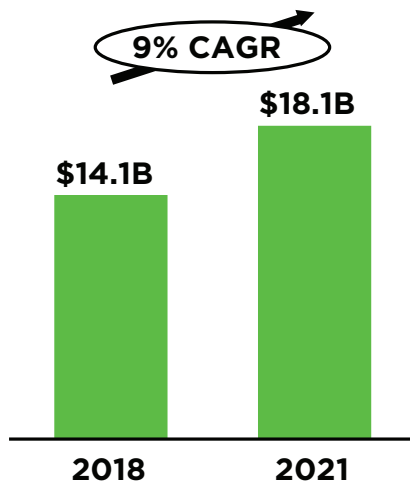
Breakdown of outsourcing by function



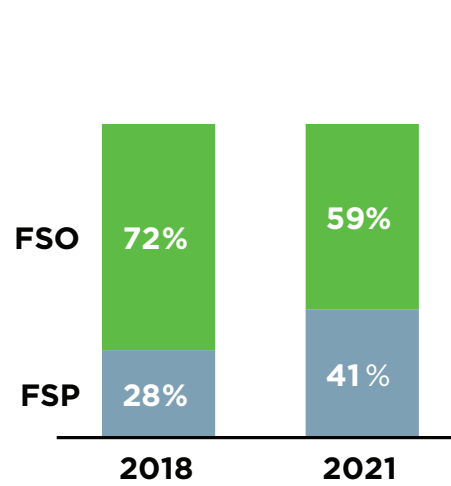
The Shift to FSP Outsourcing Models

Companies with established relationships capitalizing on the full-service model are trending to a complementary model with FSP to supplement services, such as medical writing, biostatistics and clinical monitoring. In addition, growth in hybrid outsourcing models continues, in which pharmaceutical companies use a combination of full-service and functional outsourcing.

CRO FSP Market Size, 2018-2021¹



FSP % Mix of Outsourcing²



Key Trends Impacting FSP Utilization

80%

% of sponsors increasing FSP utilization in 2021, up from just 50% in 2019⁴

13%

Annual growth in FSP usage by large biopharma³ – larger sponsors are expected to have a 50:50 split between FSO and FSP in 2021²

3-4

Number of preferred FSP providers that sponsors are likely to retain going forward – more companies in the BioPharma sector are leveraging several FSP partners over a sole-provider model

¹ISR report for CRO Market size, Avoca for FSP % (37%), 2018 size from prior FSP strategy

²Avoca research (used average of 2019 and 2020 FSP % mix to determine market size and FSP% Mix of Outsourcing in 2021) ³Applied Clinical Trials ⁴Jefferies Research

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PPD® FSP solutions

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