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How to Choose the Right Clinical Trial Outsourcing Model | PPD Inc

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An Overview of Clinical Trial Outsourcing Models – And How to Choose the Right One for Your Trial and Marketed Products

Learn the common types of clinical trial outsourcing models and how to select the best model for your needs – both today and in the future.

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The COVID-19 pandemic rapidly accelerated the adoption of clinical research outsourcing models by biotechnology and biopharma companies. By leveraging outsourcing, these companies were able to fill a geographic gap or bolster a specific type of expertise to make possible a new class of vaccines, antivirals and antibody therapies.

Experts now predict that the [global biotechnology and pharmaceutical services](#) market will surpass \$91.4 billion by the year 2028, growing at a rate of 5.2% annually.

Keep reading to learn more about outsourcing models the benefits of hybrid outsourcing.

What Are the Different Types of Outsourcing?

[Outsourcing models in clinical research](#) have evolved to accommodate the industry's changing needs. [Biotech companies](#) are increasingly looking to outsource key capabilities to gain new functionality and expertise, while being able to spend more time in-house on core competencies. This translates to operational efficiencies and growth for biotech ventures, while bending the cost and time curve of drug development.

Contract research organizations (CROs) work in various

outsourcing models that are customized to meet customers' unique needs. These models range from contracting specific functional services to providing full-service outsourcing capabilities.

For example, some of the outsourcing models offered by the PPD clinical research business of Thermo Fisher Scientific include:

- **Functional service provider (FSP):** With FSPs, clients outsource all or some portion of one or multiple functions, such as data management or monitoring. FSP models provide resource flexibility and access to specific expertise not readily available in-house.
- **Full-service outsourcing (FSOs):** FSOs are the complete outsourcing of most — if not all — tasks for a clinical development project on a trial-by-trial basis. Because this model reduces the client's management burden, the FSO approach is useful for sponsors who do not have any study-related task expertise or the resources or expertise to execute and manage the entire project.
- **Hybrid studies:** With hybrid studies, elements of FSP and FSO models are incorporated in a bespoke manner. This can drive flexibility and access to complementary expertise, as needed, for each client.

In recent years, PPD's experts are seeing clients lean more toward functional service provider and hybrid models, as clients contend with increasingly competitive talent markets for most roles, including senior positions.

Functional service provider and hybrid models enable drug developers to outsource individual functional services to gain flexibility and efficiency. Sponsors are freed to spend their time

developing core competencies in-house and can turn to their partner CRO for specialized scientific and technical services.

Examples of in-demand outsourced capabilities include clinical monitoring, data management and pharmacovigilance, as well as specific therapeutic expertise in oncology and rare diseases.

How to Choose the Best Outsourcing Model for Your Needs

More and more, sponsors today are partnering with Thermo Fisher Scientific's PPD clinical research business to deploy a combination of these models.

The most appropriate outsourcing model depends on each client's individual needs. These needs may change over time, necessitating different models. One way to streamline outsourcing operations is to choose one provider that can deliver value in many different domains.

The result is a customized solution, developed exclusively for each client, to meet specific needs. In addition, a full-scale CRO like PPD can employ a mix of operating processes. For example, PPD can work in its own systems and standard operating procedures (SOPs), use clients' systems and SOPs, or work in a hybrid mix.

When choosing the best outsourcing model, considerations include:

- **Historical precedent – and future-forward needs.** Clients tend to trust tried-and-true processes that have worked before. They may have previously relied on in-house expertise, insourced staff through FSP, or outsourced everything via FSO. But these days,

outsourcing operations can be more flexible, relying on a mix of in-house and outsourced talent.

- **Level of internal resources and expertise.** The level of internal knowledge, experience and staffing often drives what outsourcing model to use. Some clients may opt for insourcing as an alternative to hiring more in-house resources. Others may need to add complementary expertise to their team and choose an FSP model to provide a specific function. Other clients may select a fully outsourced solution because they don't have the resources or expertise to execute and manage the entire clinical development project.
- **Metrics and data.** Comparative data is the backbone for selecting the optimal outsourcing model for a project. Metrics enable an outsourcing partner to measure markers that may have the greatest impact on deliverables to help clients identify the model that delivers improved turnaround times, better data management, enhanced compliance processes or any other objective being measured.
- **How you want your model deployed.** There is no one-size-fits-all approach to successful outsourcing. Clients benefit by choosing an outsourcing partner that can help determine project-specific needs and deliver appropriate solutions — whether that includes outsourcing by geographic region, function, phase of clinical trials or post-approval, by therapeutic area or by asset.

How a Customized Outsourcing Model Drives Client Success

With each passing year, more of PPD's clients, from large pharma

to biotech, are choosing hybrid models across their portfolio of drugs or devices in development. Why? A hybrid approach allows the client to get the best from each outsourcing model to maximize their internal strengths and core competency. Some examples for consideration include:

- A biotech company may need to insource a few full-time employees to support study setup until it is ready to completely outsource a whole project or projects.
- A client has recently developed its first oncology compound in-house but does not have deep internal expertise in running an oncology trial. Therefore, they may start off with an FSO model before moving to FSP as internal expertise grows.

Another benefit of choosing a hybrid model from a CRO that provides both FSO and FSP services is that the metrics are centralized — and that process improvements driven by those metrics can be implemented seamlessly across the client and CRO. As a result, these key performance and quality indicators can be used to identify the right model for each project and uncover areas for improvement.

Benefits of PPD Functional Service Partnerships Solutions

Outsourcing involves establishing strategic partnerships that can add new efficiencies. As an alternative to keeping everything “in-house,” outsourcing maximizes quality and operational success while adding new capabilities and flexibility not found in-house.

PPD clinical research services offer top-tier outsourcing models that are structured to meet sponsors’ needs, maximizing flexibility

and providing more proactive customer service.

- With PPD's hybrid outsourcing models, clients don't have to commit to just one model. Operational data drives model decisions, proving that each PPD client can have a model that best fits their needs — FSO, FSP or a hybrid — project by project.
- The same expert talent pool feeds all of our outsourcing models. This means that all employees receive the full force of PPD's global training, professional development and infrastructure — whether working in a consultancy, FSP, FSO or hybrid outsourcing model.
- As a one-stop-shop, PPD provides extensive breadth and depth of specialists for clinical services and marketed products across all phases, therapeutic areas and experience levels in 160 countries.

PPD Functional Service Partnership solutions are an increasingly valued option for clients in how they enable biotech and biopharmaceutical companies to overcome resource challenges.

PPD FSP solutions provide clients with hard-to-find, [top-tier clinical experts](#) that, compared to other providers, provide best-in-class support, expertise, knowledge and experience. This is because all talent comes from the same highly trained talent pool. Whether a large-scale program or a small gap in services, PPD delivers unrivaled resource flexibility, reliability and continuity. Our experts partner hand-in-hand with clients and lean on data-driven insights to guide process improvements and provide high-quality service that can unleash drug developers' ability to innovate and scale.

The PPD clinical research business of Thermo Fisher Scientific

enables pharmaceutical and biotechnology companies to gain key expertise, experience and talent needed to drive innovation.

Download our [2022 Drug Development Outsourcing Trends](#) report to learn what's driving the shift to FSP services and when sponsors should consider an FSP outsourcing model.

Discover how our scalable FSP solutions can meet your clinical resource needs