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Understanding the Art and Science **of CRO Selection**

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ISR reports

Understanding the Art and Science of CRO Selection

ED BILLER

Industry Standard Research (ISR) has been collecting data on CRO selection and performance for nearly 15 years. We've watched the industry grow, service offerings expand, and providers consolidate and spin off. Through it all, we have been surveying industry decision makers to keep a finger on the pulse of how CRO selections are made and how providers have performed for their recent customers. This e-book examines the rationale behind how CROs are selected, why they are retained, and why sponsors opt for one provider or outsourcing model versus another.

"Company Size And PPAs – Peeling The Layers Of Phase 2/3 Service Provider Selection" (pp. 6-7) examines Phase 2 and Phase 3 outsourcing through the lens of organizations with and without benefit of a preferred provider agreement (PPA). While a preferred provider has been thoroughly vetted and has a contract in place, very few small companies, per recent CRO benchmarking results, have PPAs in place for Phase 2/3 services. So how do these segments proceed with provider selection when they don't have that luxury?

"What To Prioritize When Selecting A Phase 1 CRO" (pg. 8) is an infographic exploring the decision-making process behind sponsors' service provider selection for Phase 1 partnerships. Building on the previous article, the infographic takes into account the impact (or absence) of PPAs while keying in on three common, desirable attributes: operational excellence, therapeutic excellence, and access to patient populations.

"Finding A Glass Slipper Service Provider To Fit Your Phase 2/3 Outsourcing Needs" (pp. 9-11) looks deeply into why certain sponsors prefer certain types of service providers. For example, the clinical operations director at a large pharma company may prefer to partner only with large CROs for Phase 3 studies, while the seasoned project manager at a non-large sponsor company considers a midsize CRO her go-to for Phase 2 trials. By looking at the top benefits associated with different kinds of service providers, one can gather a sense of where each one excels.

"Too Hot, Too Cold – Finding the Clinical Development Outsourcing Model That Is Just Right" (pp. 12-14) compares seven clinical development outsourcing models common to the industry. About one-third of survey respondents indicated they have not found the model(s) that work(s) best for their companies. They also indicated a willingness to explore outsourcing options to ensure success of their clinical development programs, citing a variety of triggers that would prompt their companies to change outsourcing models. This article analyzes why sponsors gravitate toward particular outsourcing models, as well as what it would take for those sponsors to explore something slightly — or drastically — different.

Finally, "Outsourcers Send A Consistent Message In Phase 2/3 CRO Selection" (pp. 15-16) investigates why outsourcers seek certain providers for Phase 2 and Phase 3 studies — from efficient operation and past positive experiences with that provider to experience with similar studies and demonstrating strong data quality. The article is based on findings from two online surveys (one focused on the Phase 1 space and another focused on the Phase 2/3 space), evaluating the performance of 50 CROs across 20+ attributes, intended for sponsors to gain improved understanding of which service providers may be good fits for their needs and priorities.

Regardless whether a study is Phase 1, 2, or 3, CRO selection is a complicated exercise. As Sherry Hubbard-Bednasz notes in "Company Size And PPAs – Peeling The Layers Of Phase 2/3 Service Provider Selection," "there is no wish list that fits all. Too many factors prevent the proverbial 'easy button.'" Still, insight into different types of service providers' apparent strengths and shortcomings, combined with revelations into sponsor decision-making processes around the industry, can help sponsors to explore their outsourcing options with greater confidence. ISR

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Company Size And PPAs – Peeling The Layers Of Phase 2/3 Service Provider Selection

SHERRY HUBBARD-BEDNASZ Market Research Director, Industry Standard Research

If only there were an easy button for service provider selection. Indeed, this process continues to evolve and grow in complexity as clinical trials do the same. Layer in factors such as company size and preferred provider agreements (PPAs) and you can find yourself quickly overwhelmed by provider options and service offerings.

For good or bad, if you have PPAs in place, those providers are "in waiting." Got a trial to run? Check with your PPA list first. Whether pleased or displeased with your preferred providers, the fact is, you have a starting point. A preferred provider has been thoroughly vetted; a contract is in place. There is a transparency about what they can and can't do. You can assess whether a preferred provider can meet 20% or 80% of your trial needs checklist. For many small and emerging pharma companies, this first step is simply not available. Very few small companies, per recent CRO benchmarking results, have PPAs in place for Phase 2/3 services.

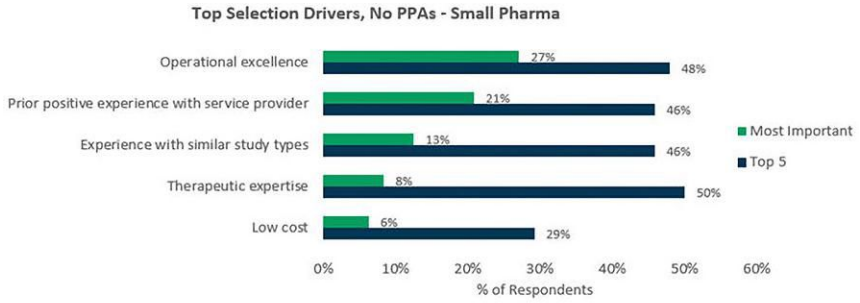
Let's take a closer look at the 237 respondents who participated in the Phase 2/3 CRO benchmarking survey. Of those, 52 respondents work at small companies (R&D less than $100M) and 185 respondents work at midsize or large companies (R&D greater than $100M). Of the 52 respondents at small companies, a whopping 92% do not have PPAs in place vs. 8% who do. Of the 185 respondents at midsize/large companies, 31% do not have PPAs vs. 69% who do.

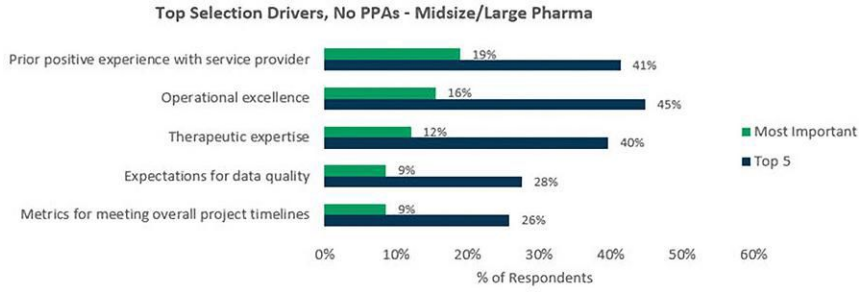
How do these segments go about provider selection when they don't have the luxury of PPAs? What tops their checklists as they search for the best-suited provider? The two charts on the next page compare the top five selection drivers for small pharma and midsize/large pharma. At least two-thirds of each subset's Most Important picks are captured in the Top 5. Some standout parallels and differences can be found between the two. In terms of parallels, having had a Prior positive experience with service provider is equally important to both segments (~20% Most Important, ~43% Top 5). Therapeutic expertise also resonates with both segments at about the same rate (~10% Most Important, ~45% Top 5).

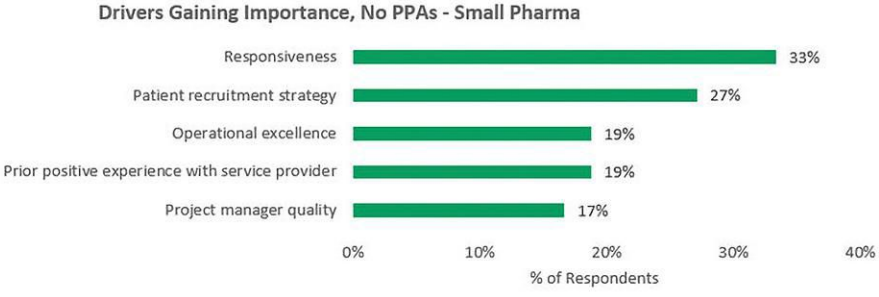
Stark differences lie with the other attributes. Interestingly, Operational excellence is notably more critical as a selection driver to small pharma (27% Most Important) compared to midsize/large pharma (16% Most Important). Experience with similar study types and Low cost captured the third and fifth positions, respectively, with small pharma yet were not on the Top 5 radar for midsize/large pharma. Likewise, Expectations for data quality and Metrics for meeting overall project timelines captured the fourth and fifth positions, respectively, for midsize/large pharma but did not make the Top 5 cut for small pharma.

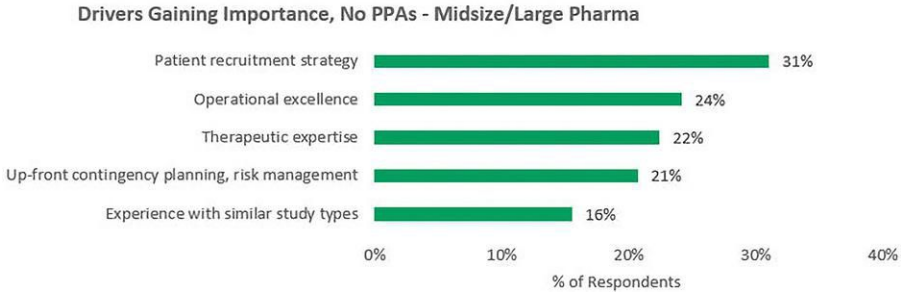
The charts on the next page reflect what respondents consider most important in their selection process at the present moment. How do respondents see this process changing, if at all? What is going to shape their selection decisions in the future? The charts show respondents' top picks for those attributes gaining importance. Again, we see parallels and differences among these two subsets in the decision-making scenario of not having PPAs in place. Not surprisingly, Patient recruitment strategy and Operational excellence still hold as important future drivers for both subsets.

The most striking difference is small pharma's top – and unique – pick of Responsiveness (33% of respondents). Occasionally, we will come across a respondent comment that alludes to this subset wanting CROs to be more attentive to their needs, both in turnaround time and priority. Small pharma's role in driving drug innovation is increasing, as is their reliance









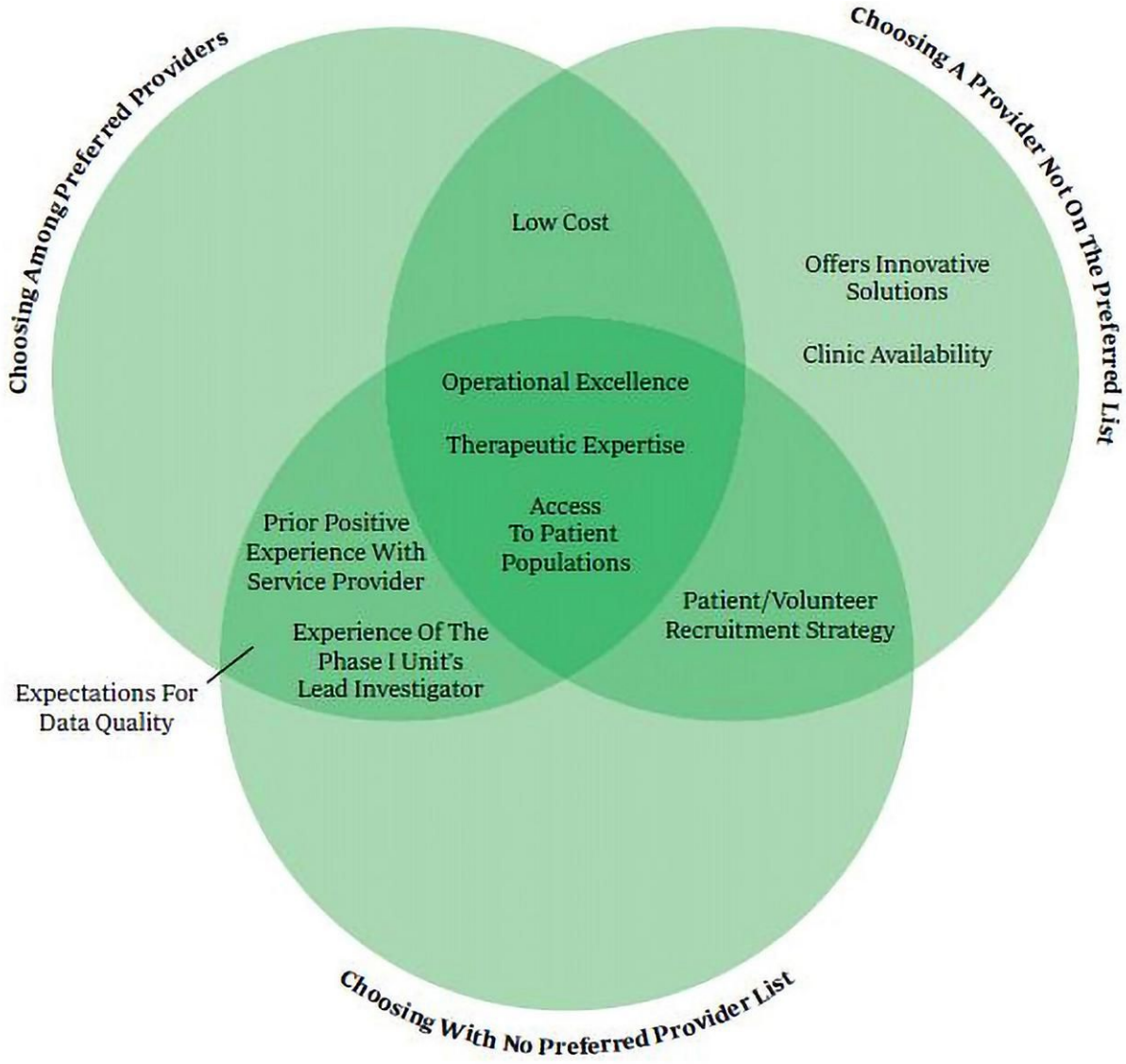
on strong vendor partnerships. Also unique to the top five selected by respondents at small companies are the attributes of Prior positive experience with service provider (19%) and Project manager quality (17%). Likewise, respondents at midsize/large companies said three attributes are gaining in importance: Therapeutic expertise, Up-front contingency planning, risk management, and Experience with similar study types (each capturing about one-fifth of respondents).

Peeling the layers on provider selection reveals this simple fact: There is no wish list that fits all. Too many factors prevent the proverbial "easy button." Even so, a slight pattern does emerge for these two subsets that do not have PPAs at their disposal. Small pharma is looking for a personal touch – there is an underlying desire to secure the human aspect of clinical trials. Get the people, relationships, and customer service right and the project work will follow. Midsize/large pharma does share in this, however, the mechanics of clinical trials – data quality, metrics, knowledge, risk management – seem to rise a bit more to the top. ISR

What To Prioritize
When Selecting A Phase 1 CRO

INDUSTRY STANDARD RESEARCH

A critical factor when examining service provider selection is the existence of preferred provider agreements. Keeping this in mind, ISR asks respondents to share their selection criteria in a way that demonstrates these agreements' impacts on the decision-making process. Three attributes are prevalent in all three scenarios: *Operational Excellence, Therapeutic Excellence, and Access To Patient Populations.* ISR



Finding A Glass Slipper Service Provider To Fit Your Phase 2/3 Outsourcing Needs

SHERRY HUBBARD-BEDNASZ Market Research Director, Industry Standard Research

It's Monday morning. The office is buzzing with chatter about the new clinical trial your company is going to sponsor. It's a big one, but the checklist of niche needs is long, including a complex indication, specialized patient recruitment, and risk-based monitoring. You have some ideas about which CROs you think would fit the bill for outsourcing needs, but it will be a difficult decision. And so the provider selection process begins...

What if you were the sole decision maker in this situation? We at ISR like to ask survey respondents this very question when it comes to key outsourcing decisions. Such decisions are rarely made by a single individual; however, an aggregate measure of provider preference can be an important piece to understanding the larger puzzle of how these decisions are made. Let's say a clinical operations director who works at a large pharma company says he prefers to partner with only large CROs for Phase 3 studies. Conversely, a seasoned project manager who works at a non-large sponsor company says a midsize CRO is her go-to for Phase 2 trials. In these scenarios, size stands out as a correlating factor. Large favors large, non-large favors non-large. Do we see this pattern among clinical outsourcers?

In a recent ISR study, we asked 121 respondents involved with outsourcing activities if the choice were completely up to them, what type of service provider(s) would they choose to help their organizations conduct clinical trials. Respondents were asked their preference for Phase 1, 2, 3, and 4 trials. The charts below provide evidence of the relationship between company size and provider type preference for Phase 2 and 3 studies.

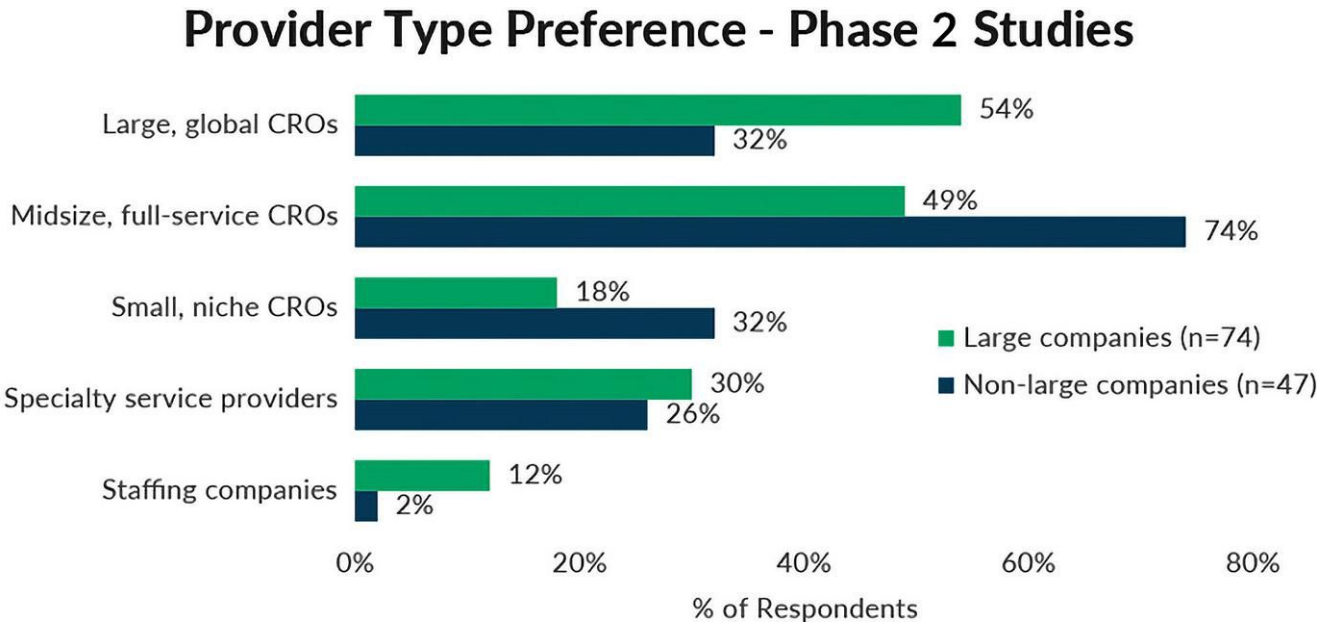
There are notable differences in preference nearly across the board for Phase 3 trials. More than half of respondents (54%) at large sponsor companies prefer large CROs for Phase 3 work compared to one-third of respondents (32%) at non-large sponsors. Three-quarters of respondents (74%) at non-large companies prefer midsize CROs compared to half of respondents (49%) at large companies. Likewise, one-third of respondents (32%) at non-large companies prefer small CROs compared to one-fifth of respondents (18%) at large companies.

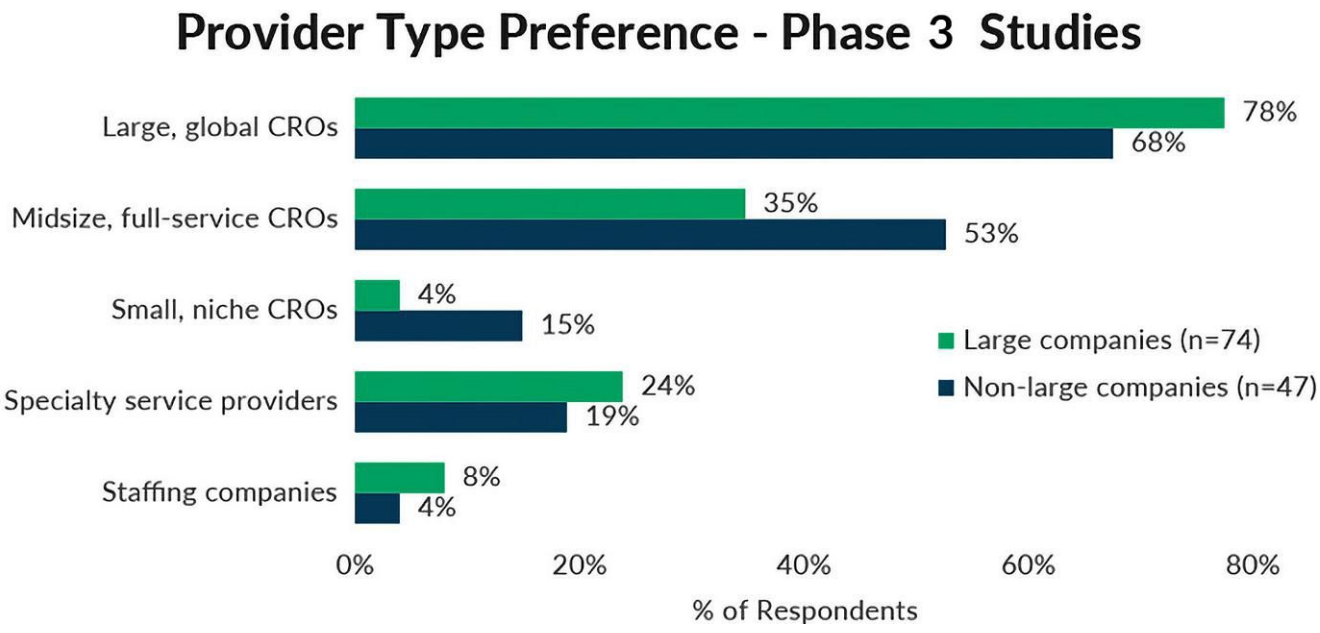
Provider preference tightens up a bit for Phase 3 studies. Large CROs were the top provider choice by respondents at both large and non-large sponsor companies for Phase 3 trials (78% and 68%, respectively). More respondents at non-large companies favor midsize full-service CROs (53%) versus one-third of respondents (35%) at large companies. Likewise, preference for small CROs resonates slightly more with respondents at non-large companies.

There's no denying it. Size plays a part in provider preference but it's not the only thing. The service provider market is vast and the provider selection process is complex. While a handful of large CROs account for about half of the CRO services market share, other service providers continue to carve out their piece. Do provider types vary in terms of perceived advantages over others? In a word: absolutely.

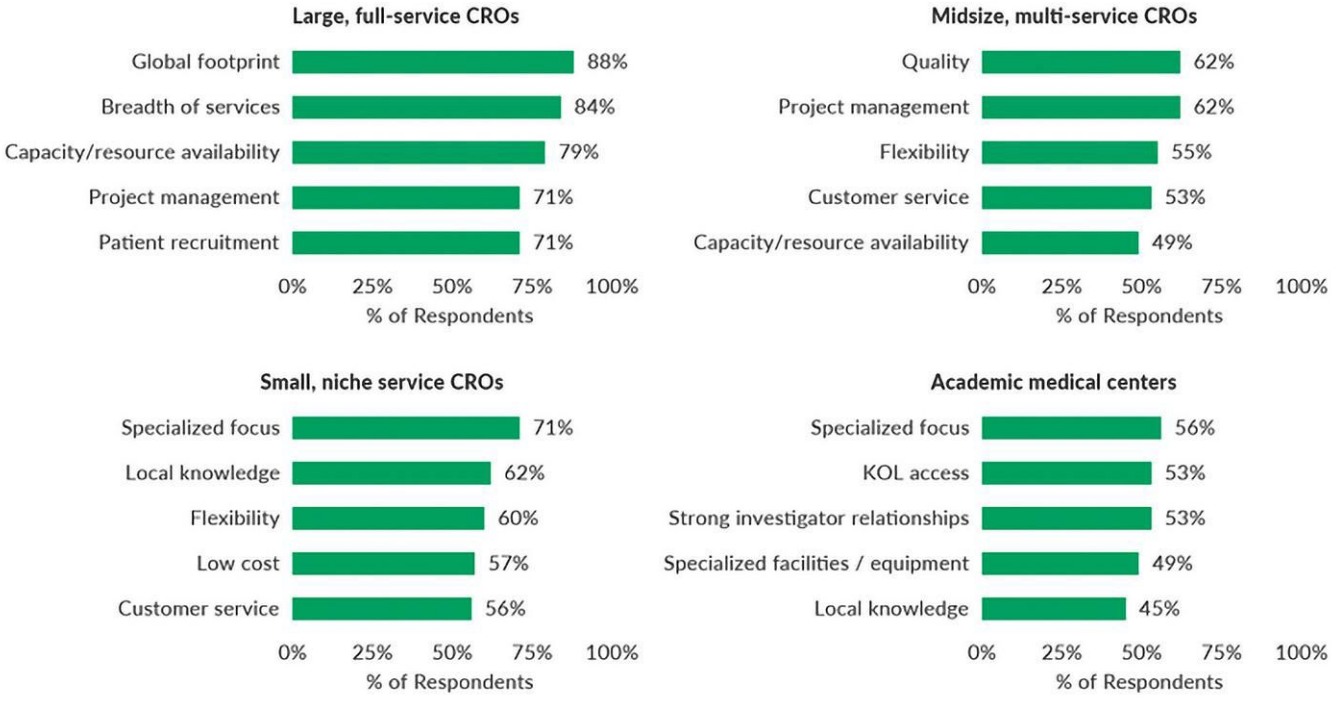
In another recent ISR study, we asked 146 respondents what unique benefits, if any, do they associate with using four types of providers for Phase 2/3 services: large full-service CROs; midsize multi-service CROs; small niche service CROs; and academic medical centers. The charts on the next page highlight the top five benefits reported by respondents for each provider type.

The dominance of large CROs is hard to ignore. Several attributes, according to respondents, are exclusive to large CROs – no other provider type claimed Global footprint (88%), Breadth of services (84%), and Patient recruitment (71%) as a top five benefit. Nearly two-


Provider Type Preference - Phase 2 Studies
Large, global CROs
54%
32%
Midsize, full-service CROs
49%
74%
Small, niche CROs
18%
32%
Specialty service providers
30%
26%
Staffing companies
12%
2%
Large companies (n=74)
Non-large companies (n=47)
0%
20%
40%
60%
80%
% of Respondents


Provider Type Preference - Phase 3 Studies
Large, global CROs
78%
68%
Midsize, full-service CROs
35%
53%
Small, niche CROs
4%
15%
Specialty service providers
24%
19%
Staffing companies
8%
4%
Large companies (n=74)
Non-large companies (n=47)
0%
20%
40%
60%
80%
% of Respondents

Top 5 Benefits of Different Provider Types



thirds of respondents (62%) said Quality is a top five benefit associated with midsize CROs, and exclusively so. Both large and midsize providers, however, tout Capacity/resource availability and Project management as shared top five benefits.

Specialized focus is a top five benefit exclusive to small CROs and academic medical centers, per 71% and 56% of respondents, respectively. Low cost (57%) is associated with small CROs as a top five benefit but not with others. Several top five benefits are exclusive to academic medical centers, including KOL access and Strong investigator relationships (53% each) and Specialized facilities/equipment (49%). Both small CROs and academic medical centers, however, share Local knowledge as a top five benefit. Midsize and small CROs share two attributes: Flexibility and Customer service.

Clearly, each provider type has a few gold stars on which to strategically position its clinical development services offering. Granted, many attributes were selected by at least one-third of respondents across provider types, perhaps evidence of service providers' efforts to become more agile. By looking at the top five benefits, however, one can gather a sense of where different service providers shine. Such information helps to make that glass slipper – or in today's clinical trials, a pair of steel-toe boots – just a little easier to find. ISR

Too Hot, Too Cold – Finding The Clinical Development **Outsourcing Model That Is Just Right**

SHERRY HUBBARD-BEDNASZ Market Research Director, Industry Standard Research

Let's take a trip down memory lane – the good old days of original straightforward outsourcing. Have a gap in capacity? Outsource. Need access to research experience? Outsource. Pluck that card off the Rolodex and make the call to secure high quality at the best price. (Maybe we're overstating the simplicity of the good old days a bit, but that's what people do.)

Nowadays, the reasons to outsource extend well beyond a single need for a single project. Gone are the easy buttons and linear decision-making. A significantly reduced in-house development infrastructure means a heavy reliance on external resources. And with that comes challenges in managing those external relationships and expectations.

Despite the intricacies of outsourcing, the trend continues to hold. Industry Standard Research learned in a recent survey that 61% of clinical development work is currently outsourced, on average. This metric is specific to the outsourcing community; those involved with in-house only activities are not included in this figure.

Let's say you are sponsoring a novel clinical study that requires therapeutic expertise not available in-house, specific geographies, and remote/risk-based monitoring. In the past, this scenario would have been rare. Today, not so much. Let's also say this study is one of several in your pipeline. Are companies engaging more than one outsourcing model to meet their needs? Yes, and with a little trial and error.

We asked 121 respondents about their use of seven clinical development outsourcing models common to the industry. For the purposes of the survey, models were defined as the following:

Compound or Program-Based	A sponsor outsources all or most development for a specific compound or program of compounds to one provider
Fee-For-Service	A sponsor outsources clinical development projects on a trial-by-trial basis (traditional CRO outsourcing)
Functional Service Provider (FSP)	A sponsor outsources all or most of one function (data management, monitoring) or therapeutic area or work in a geography to a service provider
Hybrid Full-Service and FSP	A sponsor uses outsourced resources for a project that are specific to that study and those from an established FSP pool of resources; these resources do not have to come from the same provider
In-Sourced	Personnel are brought in from a staffing agency or other service provider and placed under the sponsor's management for a defined period of time
Preferred Provider	A sponsor selects a few service providers and these providers are awarded most of the sponsor's outsourced clinical development work
Sole-Source	A sponsor selects one partner for all its outsourced clinical development work

We found that all but one model surveyed somewhat missed performance expectations when ratings were assigned point values. The In-Sourced model was the only one that performed slightly above expectations. Moreover, one-third of respondents disagreed with the statement that they have found the model(s) that work(s) best for their companies.

So what outsourcing models are companies using? The chart below shows the utilization of each model by large (R&D spend of $1B or more) and non-large (R&D spend of $100M-$999M) companies. At least 10% of clinical development work was required to be conducted per a given model to be counted toward utilization of that model.

The Preferred Provider model is utilized most overall; however, a greater percentage of respondents from large companies (82%) reported use of this model compared to respondents at non-large companies (57%). Conversely, a greater percentage of respondents from non-large companies reported use of the Fee-For-Service model (47%) and Compound or Program-Based model (53%) compared to respondents at large companies (39% and 38%, respectively). Non-large sponsors may be less inclined to lock into formal preferred provider contracts, allowing them to shop around for the best-suited CRO and/or competitive bids.

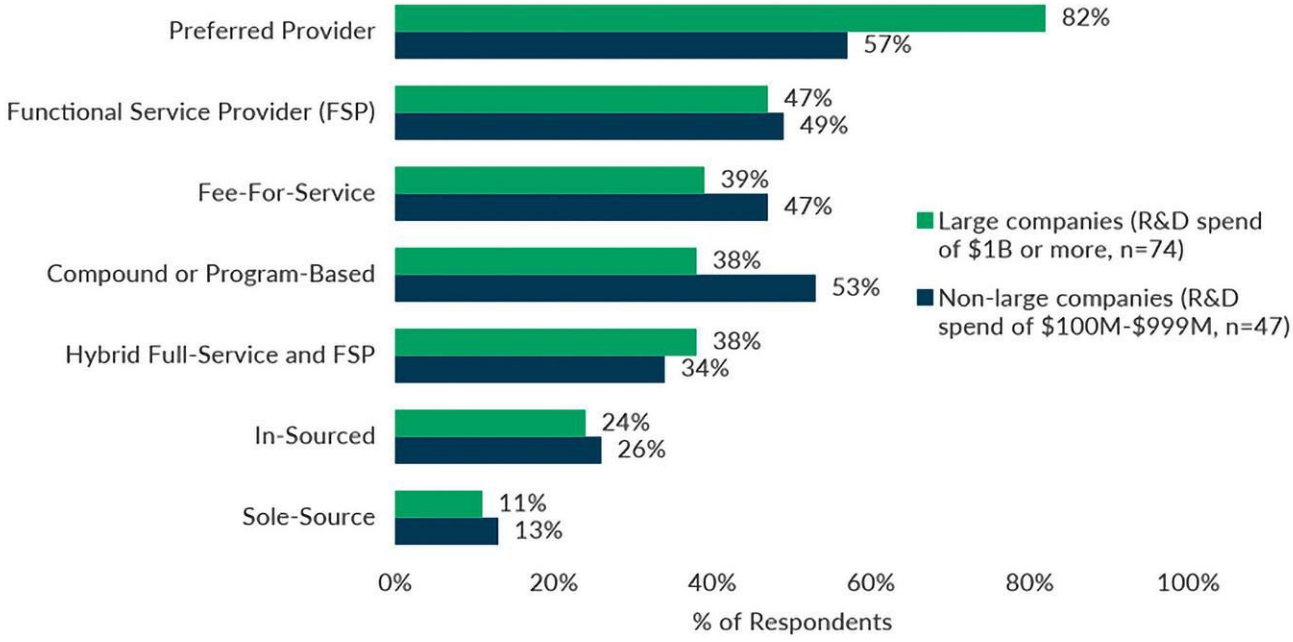
All but one outsourcing model in the chart above are utilized by at least one-quarter of respondents. This tells us that companies have options, and they are exploring them. Another aspect to consider is this: What a model may offer on paper versus how the model is executed by a provider may not line up. Indeed, the advantages and disadvantages to using these models differ.

We asked respondents to choose from a pick list the benefits and drawbacks they experience from using a given outsourcing model. Some models share similarities, and some, like the three in the table below – Preferred Provider, Fee-For-Service, and In-Sourced – substantially differ from each other. While the Preferred Provider model cultivates established partnerships, the Fee-For-Service model fills gaps regarding expertise, skills, and technology. The In-Sourced model optimizes staffing needs. Downsides are unique as well; however, a high price tag is shared. In fact, all seven models flagged high cost as a top three drawback.

In addition to capturing pick list pros and cons, we learned in respondents' own words why they use a particular model for outsourcing clinical development work. Such comments are a window into sponsors' actual situations and needs.

One respondent shared this reason for why they use the Fee-For-Service model: "We are a small company (700 employees) with various compounds in multiple therapeutic areas. This approach lets us find the best providers with specific therapeutic experience." Contrast this with another respondent's reason for using the Compound or Program-Based model: "Large programs centered around one com-

Outsourcing Models Conducting Clinical Development Work



	Top Benefit	2nd Benefit	3rd Benefit	Top Drawback	2nd Drawback	3rd Drawback
Preferred Provider	Vendor consolidation, fewer relationships to maintain	Improved service provider relationships/ deeper partnerships	More efficient clinical development activities	High cost	Reduced resource flexibility/locked-in contracts	Lack of ultimate control
Fee-For-Service	Increased resource flexibility	Access to specific skills/expertise not available internally	Access to technology not available internally	Lack of integration with other employees	High training/ onboarding time/ resources needed	High cost
In-Sourced	Increased resource flexibility	Access to additional core resources (tie 2nd)	Lower employee turnover (tie 2nd)	High training/ onboarding time/ resources needed	High cost	Difficult HR process/procedures

pound can cross-fertilize easily with this outsourcing; information is not diluted or lost in communication within one single organization."

The second most utilized model, Functional Service Provider (FSP), also garnered distinct reasons for use, including remote work and cost savings. One respondent shared: "Some activities lend themselves to hiring a specialized workforce, especially for work that can be done remotely and/or is very objective in nature. The FTE costs are far lower than for in-house staff." Another respondent reflected on scenario-specific needs met by this model: "For niche studies where we have a lot of DNA sampling or biomarkers evaluation, especially in rare disease trials or mega outcome studies conducted globally, preference is to go for a functional service provider."

Comments like these point to the increasing complexity of today's trials. And companies are willing to explore their outsourcing options to ensure success of their clinical development programs. Many respondents cited a variety of triggers that would prompt their companies to change outsourcing models. Cost implications, shift in workload, and quality of service were collectively mentioned by half of respondents. Sorting through the options and finding a model that works is indeed a work in progress for many. ISR

Outsourcers Send A Consistent Message In Phase 2/3 CRO Selection

REBECCA MCAVOY VP of Market Research, Industry Standard Research

Industry Standard Research (ISR) has been collecting data on CRO selection and performance for nearly 15 years. We've watched the industry grow, service offerings expand, and providers consolidate and spin off. Through it all, we have been surveying industry decision makers to keep a pulse on how CRO selections are made and how providers have performed for their recent customers.

Through two online surveys, one focused on the Phase 1 space and another focused on the Phase 2/3 space, recent customers have evaluated the performance of 50 CROs across 20+ attributes. For the CRO Leadership Awards, data for each CRO are aggregated across Phase 1 and Phase 2/3 services (when applicable) and compared to the performance of other CROs in the study. Leadership Awards are given to top-performing CROs in 10 different categories, so that sponsors can gain an understanding of which service providers may be good fits for their needs and priorities, and CROs can better understand how their recent customers view their performances.

While the performance data is critical for sponsors to make informed provider selections, it is also important for decision makers at sponsor organizations to assess how much value they place on performance or expertise in a variety of areas based on internal needs. For example, one sponsor may need a high degree of therapeutic expertise from its CRO while a selection team at another sponsor may instead require a low-cost CRO or a provider with specific regulatory knowledge.

Because CRO selection environments can differ among and even within companies, ISR collects respondent insights into CRO selection in a few different situations. Respondents share how they select CROs 1) among a list of preferred providers, 2) when a preferred provider list exists, but they are selecting an off-list provider, and/or 3) when no preferred provider list exists. Some selection attributes are important across all three scenarios while others are only considered top attributes in one or two of the scenarios.

2022 PHASE 2/3 CRO SELECTION

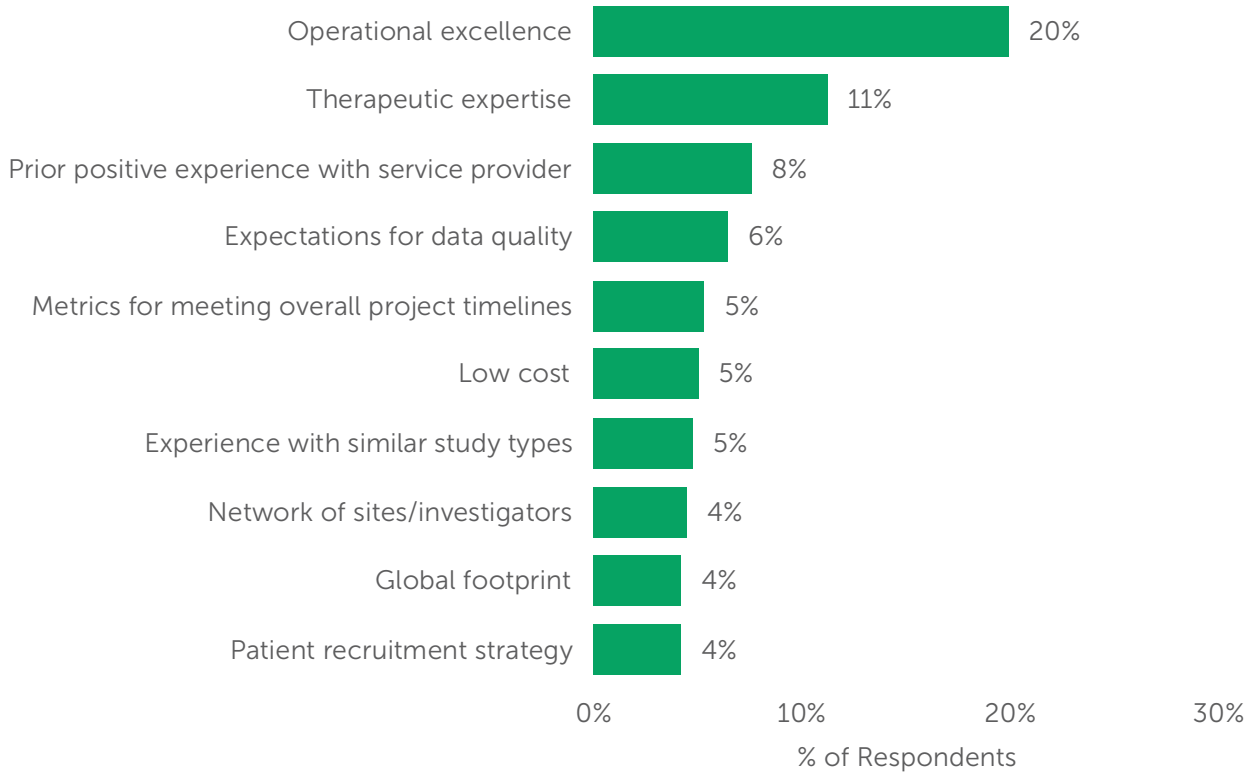
To give a high-level perspective on Phase 2/3 CRO selection, we have aggregated the selection data across the three above-mentioned decision-making scenarios. As shown in the chart on p. 16, one attribute stands out at the top of the chart. Operational excellence was selected as the most important attribute by one-fifth of respondents this year, selected at nearly double the rate of the second attribute. The size of this gap demonstrates the importance that industry outsourcers place on operational excellence when assessing service providers for their Phase 2/3 studies.

Therapeutic expertise sits in the second position, being chosen as the most important CRO selection attribute by 11% of respondents. Then, the attributes start to get closer together; prior positive experience with service provider is in third position (selected by 8% of respondents), followed by expectations for data quality (6%) and several other attributes in the 4-5% range.

PHASE 2/3 CRO SELECTION OVER TIME

The chart compares the importance of various attributes for Phase 2/3 CRO selection in 2022. However, ISR has been collecting these data for quite a while now, so we have taken a look back to ascertain whether or not these top selection factors have changed over time.

Most Important Phase 2/3 CRO Selection Attributes (2022)



We compiled the importance rankings of selection attributes going back to 2016 to understand the degree of consistency there has been in how sponsors are choosing their CROs. The story these data tell about the very top decision-making criteria is quite clear. Operational excellence has been chosen as the most important attribute by those outsourcing Phase 2/3 work every year, without exception, while therapeutic expertise and prior positive experience with service provider have typically traded off second and third positions.

We start to see some variation over time after the top three attributes. As can be seen in the 2022 chart, this is the point in the data where we get into the tightly grouped attributes that 4%-6% of respondents are considering as most important, so some variation is expected. Experience with similar study types and expectations for data quality have featured among the top-ranked attributes in many years, but not as consistently as the previously mentioned attributes. Expectations for data quality has risen in the rankings over the past few years, so this may be an area that warrants increased attention from service providers. Metrics for meeting overall project timelines squeaked into the top five attributes for the first time this year, perhaps partly due to the uncertainty and stress around timelines during the COVID-19 pandemic. ISR will continue to watch this attribute to understand if this year is an anomaly, or if meeting project timelines remains among the top considerations over the coming years.

Analyzing this historical data shows that outsourcers of Phase 2/3 clinical trial work have been sending a consistent message over time. They seek providers that can operate effectively and efficiently, know their therapeutic areas well, and that they have had positive experiences with in the past. Showing experience with similar studies and demonstrating strong data quality are likely in a second tier of consideration. CROs should feel confident in focusing their efforts on these key criteria, ensuring that their capabilities and knowledge are robust and that they communicate their strengths and prior experiences in these areas to prospective buyers. ISR

Survey Methodology: Industry Standard Research is a full-service market research provider to the pharma and pharma services industries. ISR's CRO Quality Benchmarking research is conducted annually via an online survey. For the 2022 CRO Awards data, 50 service providers were evaluated on 20+ different performance metrics. Research participants were recruited from biopharmaceutical companies of all sizes and are screened for decision-making influence and authority when it comes to working with CROs. ***Respondents only evaluate companies with which they have worked on an outsourced project within the past 18 months.*** This level of qualification ensures that quality ratings come from actual involvement with a business, and that companies identified as leaders are backed by experiential data.
For more information, please visit www.ISRreports.com.

WE'VE DONE THE WORK. YOU MAKE THE DECISIONS.

Whether you need to better understand the competitive landscape, outsourcing drivers, or important selection criteria, our experts analyze first-hand data from industry peers to equip you with valuable market insight and compelling recommendations.

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Where Did the Participants Come From?
Eliminating sample bias translates into accurate competitive information and improves service quality by ensuring your decisions are the right ones. Our Health Panel provides an array of participants from all company sizes within the pharmaceutical industry.

When Were the Data Collected?
This should be the first question you receive during a presentation and saying "I don't know" doesn't sound so good. In all our research products, we collect up-to-date data relevant to the project at hand.

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We're an independent, third-party data source. We provide clean unbiased data and clean data means you can confidently stand behind your analysis and presentations.

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Nothing stops a presentation faster than management questioning the basis of your research. Confidently project the research knowing that we pull information from key decision-makers.

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