



INSIDE

CRO

YOUR GUIDE TO KNOWING WHAT CRO ACTUALLY IS

Perfect partners: the key to fruitful and lasting relationships

Creating successful clinical development plans in a changing environment

CRO capabilities chart

Perfect partners: the key to a fruitful and lasting relationship

Kevin Olson, CEO of Industry Standard Research details the best way to find the perfect contract research organisation partner for you

It will be news to nobody with tenure in the drug development industry that the role of contract research organisations (CROs) has evolved over the past 30 years. Like other industries that rely on outsourcing, the drug development and commercialisation outsourcing sector has evolved from one with limited responsibility and limited trust to one of extensive responsibilities and – if not trust – at least acceptance.

Brief history of CRO contribution

CAPACITY

In its initial stages in the 1980s and 1990s the pharmaceutical industry used CRO resources almost purely as overflow capacity, a short-term supplement to internal headcount, in much the same way sponsors use dedicated staffing companies (ie, Kelly Services, Manpower, etc.) today. Sponsors were price sensitive and expected only modest value-add in exchange.

CAPABILITY

After moderate trust and acceptance were earned in these early years, the CRO industry began to pitch its services, differentiating from one another through the quality of the staff they could offer sponsors. They were selling expertise. And sponsors were beginning to buy it.

VALUE

Currently, another development is underway. Sponsors widely accept that CROs offer expertise and quality staff that are on a par with in-house resources. In fact, a meaningful proportion of current CRO staff have sponsor experience on their resumes. This trust – and a lot of financial pressure on sponsors – has led to an increasing reliance on CROs and their infrastructure to deliver value, save money and increase the productivity of sluggish pipelines.

Outsourcing models

As CROs have expanded their services and the value they deliver, sponsors have adopted a host of models that guide their outsourcing practices. These range from the occasional but uncommon use of staffing companies for temporary needs to the complete outsourcing of a sponsor's development operations. There is a contingent of sponsors that continue to outsource on a project-by-project basis; others find added value in outsourcing

complete programmes of studies to CROs; some outsource entire functions like data management or clinical monitoring; while others outsource everything.

In spite of the growing sophistication in outsourcing models, the outsourcing process has a tendency to be quite unsophisticated. Most sponsors will walk through a checklist that includes criteria such as global capabilities, they will count and compare the number of studies a CRO has managed in certain therapeutic areas, they will ask for competitive discounts for a volume of studies, and they will likely canvas their project team or broader organisation for feedback on a CRO's prior performance.

This process is usually designed to answer the question: "Is the CRO capable of delivering the study?" But unless you are evaluating smaller, niche CROs to perform uncommon or specialised tasks, hasn't that question already been answered? The large and mid-size, multi-service CROs are all fundamentally capable of delivering 80 per cent of the projects that are outsourced. Wouldn't sponsors be better served by asking not "Can this CRO do the work?", but rather, "Is this CRO the best fit for our organisation's needs?" Doing so will lead to a more honest evaluation process that yields a deeper understanding of not only the CRO, but also the sponsor.

Over the years, Industry Standard Research (ISR) has carried out numerous pieces of market research that have identified certain categories of sponsor needs, which could be termed as 'buying segments'. These include:

1. **Excellence in project management:** These buyers emphasise, above all, strong management of their trials with timely communications, strong timelines management and no surprises
2. **Operational independence:** These buyers may be described best by the mantra: "You're the expert. That's why I've hired you." Accordingly, there's a premium on trust and competence. Perhaps this describes many smaller sponsors
3. **Low cost/value:** This segment reflects the price-sensitive. Yes, they still require quality delivery but they are willing to tolerate some mis-fit if the price is right
4. **Global trials:** There's no doubt that a special set of skills is required as the size and scope of a trial reaches large, global proportions. Your decision criteria should include additional appropriate capabilities.

Example evaluation tool

SERVICE PROVIDERS		EXCELLENCE IN PROJECT MANAGEMENT										
		Timely project communications	Therapeutic expertise	PM quality	Minimises change orders	Meeting schedules and timelines	Meeting overall project timelines	Meeting database lock timelines	Meeting first patient first visit timelines	Speed of Site start-Up	Overall value	Consider for shortlist
LARGE CROs	Covance											
	ICON											
	INC Research											
	inVentiv											
	PAREXEL											
	PPD											
	Quintiles											
MID-SIZE / SPECIALTY CROs	Accenture											
	Charles River											
	Chiltern											
	DCRI-Duke											
	PRA											
	UBC											
	World Wide Clinical Trials											

Ratings Key:



Clear leadership



Better than most



About average



Falling a bit short



The rest

This is just an example of how ISR evaluates service providers. Use the template, modify it or create your own

With the above evaluation tool as a backdrop, here are ISR's recommendations for an enhanced selection process.

1. Consider your company's unique needs

To reiterate, this is not just from the perspective of capabilities but also from a cultural fit and work style point of view. Interview your internal project teams. Ask questions such as: "Think about your last successful engagement with a CRO: what made that engagement successful?" We

guarantee they will not answer with: "The average years of experience of their CRAs" or "They were 15 per cent cheaper." Also ask about their last frustrating engagement with a CRO. Keep digging until you get to a root cause. Maybe it was simply that timelines were missed. Or maybe the issue was actually about how the CRO didn't anticipate certain challenges or communicated the challenges poorly to the project team. Don't be tempted to conclude that these are 'soft characteristics' that can't be measured or

Consider your company's unique needs

Determine CRO performance and delivery styles

selected for ahead of time – they can be. These nuances make a difference because they encourage you to challenge future CRO partners differently.

2. Leverage internal and external resources for insight into CRO performance and delivery styles

Yes, in one sense service quality depends almost solely on the people who deliver the study – the sponsor project manager, the CRO project manager, engaged clinical investigators, diligent CRAs, etc. If you get a different supporting cast each time you buy that company's services, shouldn't you expect service quality to fluctuate? If industry turnover is high and CROs simply pass important staff back and forth, shouldn't we expect any differences in delivery quality between and among service providers to simply wash-out over time? Possibly, but that's not what happens, at least not for all providers.

CRO personnel are supported by sites, infrastructure, processes, training, SOPs, learning and development budgets, cultural dynamics and endless other factors that lead to some organisations being meaningfully more effective than others. Some organisations simply rise and fall with the tide.

Explore the strengths and weaknesses of all CROs within your criteria by interviewing a dozen project managers and medical directors from your own company. Capture their experiences, but keep things in perspective. There's more to uncover and an entire industry of experience at your disposal. Look outside your organisation as well; there are third-party resources you can lean on to gain experience beyond the walls of your own company.

- Leverage quantitative syndicated studies that measure and report on CRO quality
- Network with others on LinkedIn and tap into their experiences and expertise
- Start LinkedIn discussions on the topic of CRO delivery.

3. Challenge CROs during the bidding process to demonstrate how they will address your stylistic needs

The business development/sales staff are (or should be) fairly polished in explaining how their company is set up to deliver your study successfully. They will walk you through a deck of slides that detail corporate experience, therapeutic expertise, the average tenure of their CRAs, etc fluently. Don't forget, these things are necessary but not sufficient. Your research

into their other capabilities – work styles and practices – will empower you to dig deeper into the factors that will make for a successful partnership.

If, for instance, your internal conversations suggest that your organisation values project management excellence above all else, and your third-party research indicates that CRO X has a tendency to be more reactive to project challenges than proactive, you can raise the issue. Imagine being able to challenge a potential CRO partner with the following question... "Our data indicate that your organisation tends to struggle with anticipating project challenges. What mechanisms or processes can you put in place to ensure that this won't be an issue for our study?" That's strong, professional and everyone wins. Your needs are more likely to be met because your new partner now knows what to expect from you as a unique buyer with individual needs.

4. Write it down and measure it

You may have heard the adage "what gets measured gets done." It is no good carrying out background research, challenging your new partner, coming to an agreement and then not put the information to work. Put the new metrics and processes in the contract, measure them and expect your partner to deliver and report on them.

As the industry continues to mature, the playing field will continue to evolve. As this happens, be on the lookout for opportunities to be smarter outsourcers. Not just for contracting and pricing, but also for fit. Beyond the standard metrics of clean data and budget management, the right fit will define successful relationships.



The Author

Kevin Olson is CEO of Industry Standard Research. Industry Standard Research (ISR) is the premier, full-service market research provider to the pharma and pharma services industries. For more information visit www.ISRreports.com, email info@isrreports.com or follow ISR on Twitter @ISRreports.

**Challenge potential
CRO partners**

**Write it down
and measure it**