

# Great Size ≠ Great Value: How Smaller Outsourcing Partners Benefit Small And Emerging Biotechs

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Large clinical research outsourcing partners tout extensive expertise or experience based on past success. But pulling back the curtain on this “corporate memory” often reveals inefficiencies caused by “that’s the way it’s always been done” thinking.

Sponsors seeking an outsourcing partner to shepherd their novel drug product through clinical trials all face the same challenge: identifying a partner that combines high quality and expeditious service with an emphasis on cost mitigation. All potential partners — from the largest contract research organization (CRO) to the most niche “boutique” outsourcing operations — will claim the necessary capability to meet your every need.

Some outsourcing organizations tout a low (initial) cost or some application of unique technology. Others point to their past accomplishments or sell their process. The most valuable asset an outsourcing partner can offer is high-quality personnel, each experienced in their current role and passionate about its undertaking. The challenge for sponsors is how to identify partners that can consistently provide such talent across the life of their project, teams of individuals whose expertise is custom-assembled for that project.

The biopharma industry spends tens of billions of dollars annually on contract research and outsourced clinical trial management services. This market is growing and has attracted numerous players, complicating sponsors’ search for a partner whose capability, cost, and process meet their needs. Knowing where to start the search, as well as the best questions to ask when a potential outsourcing partner has been identified, eases this effort considerably.

## **BIG-BOX CROS AND THE CULTURE OF MEDIOCRITY**

The allure of big-box CROs is clear: they have worked on every kind of drug hun-

dreds of times and they have been in business for decades. Their initial pricing is attractive (and does not vary much between competing giants), and the timelines they promise are colored with optimism. But the surety you’re promised — the knowledge your product is in seemingly capable hands — is like an island of ice seen bobbing atop the waves, while a massive iceberg of uncertainty lurks just below the water’s surface.

This is not to demonize large CROs, as they do bring to bear abundant resources and global reach, serving well the deep pockets and spectacular ambitions of pharma giants. The reality is that most sponsors are small or midsize organizations, not international pharma juggernauts. These more modestly sized organizations share the same market ambitions, but do not wield the same pocketbooks — hence, power — in their dealings with large CROs. They cannot accept the same risks or survive the same setbacks.

Yet, we have been conditioned as an industry to believe that large CROs usually are the best partner and that many of the avoidable problems linked to that choice are inevitable, leading to an unconscious acceptance of mediocrity. Consider, for example, these “benefits” of partnering with a big-box CRO:

**Comprehensive product and service offerings** — Like a chain restaurant with wagon wheels or sports memorabilia on the walls, or a massive car dealership with thousands of cars on the lot and espresso machines in the showroom, a large CRO must roll its overhead costs into its offerings. However, most companies developing

a new drug don't need all the perks; they need focused expertise in a particular therapy area. They require an efficient drug development process based on specific knowledge and experience, driven by a motivated team that exhibits personal attributes of excellence. They cannot overspend on bells and whistles that they will not utilize, especially while relying upon series funding or early venture funding. They need to achieve an end point that allows more fundraising to take place.

Change orders are another common, costly occurrence when working with large CROs. One industry adage states that whatever the sponsor's initial spend with a CRO, expect to tack on an additional 20% through change orders. This is understandable if the sponsor requests changes that necessitate a change order, but why should that sponsor foot the bill when the CRO makes a mistake? Such a scenario is illogical, but it has become normalized in this space.

**Industry and process knowledge —** "Corporate memory" is a myth; nonetheless, name recognition and past successes represent a large part of CRO allure. Organizational fame and yesterday's wins have little influence on the company's performance relevant to your particular project. By that logic, the New York Yankees should win the World Series this year based on their championship legacy, despite having different players in different roles, as well as facing different opposition each season. This is the context in which the untested decision maker operates. Changing personnel and shifting industry dynamics must be acknowledged when seeking an outsourcing partner.

Consider the impact CRO staffing inefficiencies have on your project. Turnover and, even more so, attrition are traditionally high at a CRO. CROs usually must promote highly talented people quickly to retain them; therefore, your project manager may change mid-stream. Additionally, delegation of responsibility may lead a large CRO to assign more and more of your project to junior personnel as it progresses, since the highly talented individ-

uals are limited and likely to be assigned to the next big project coming in the door. As a result, the people you deal with who can make decisions that drive creative change are diminished in both quantity and quality.

Many CRO proposals boast experience across "hundreds" of studies within a specific indication while never providing any context to substantiate that claim. In truth, the impact of general corporate experience is minimal, at best. It is recommended to weigh such claims against the following considerations:

- Are the people who worked on and managed those previous studies still working for the vendor?
- Are they still serving in the same role?
- Are those who performed day-to-day tasks for the previous studies available to be assigned to your program?
- Can their assignment to your study be guaranteed for its full duration?
- If so, will you have to pay a premium to have that resource assigned?
- Are you provided assurances that each initiated investigative site will enroll the required patients?

Operational heads have control in this industry when they have confidence the work they want performed is being faithfully conducted. A feeling of trust in your outsourcing partner's capability and business integrity is the foundation of that control. If you cannot believe your teammates will play their role, how can you do your own job without looking over your shoulder, or waiting with dread for something to go wrong?

Examples of non-control might include a project that has cycled through four project managers in six months. Perhaps you need a snapshot of your data and cannot get it, or you have to pay to see the status of your trial master file (TMF), even though this is your study. You should not have to wait for data because your outsourcing organization has yet to hire

enough personnel for the project. Sponsors experiencing delays because of their partner's frailties have lost control.

In that same vein, vulnerability in this industry is defined as getting a result you were not promised. Vulnerability is eliminated when you have confidence the project team at your disposal is as astute and as detail-oriented in managing this experiment as you are. When that dedication aligns across partners, high-quality data is generated and accurately captured, allowing you to make well-informed decisions that serve the best interests of your company, your study, and most important, the patients you are serving.

## CONCLUSIONS

The bigger-is-better system has not worked for many small, midsize, or otherwise emerging companies. inSeption Group offers a solution.

We selectively limit our areas of therapeutic expertise to those indications where we have found talented individuals are most excited to participate. We believe that elite teams of functional experts, custom assembled for a specific purpose, deliver transparency, precision, and certainty to an industry that is rife with complexity and disappointment.

It is inSeption's foundational belief that, guided by principles of integrity and service, driven by collaboration and a burning desire to write success stories for our clients, our proprietary methodology and process enable us to identify the right resource for each client, with the right message, at the right time — every time.

For more information, visit inSeption Group online at <https://www.inseptiongroup.com/>.

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## ABOUT THE AUTHOR

Joe Arcangelo is the Co-Founder and Managing Partner of inSeption Group. His unwavering passion for challenging the outsourcing industry's status quo and changing the current paradigm was the inspiration behind inSeption.

With over 35 years of experience in the biotech and pharmaceutical industry, Joe brings a unique perspective — having witnessed the dawn of outsourcing organizations, the ensuing years of explosive growth, and the industry as it has settled today.

Based upon a foundation of character and principles, as well as dedication to patients, colleagues, and the clients we serve, Joe's vision and results-oriented approach have benefited his partnerships with overall success.

## ABOUT inSEPTION GROUP

Unified in our passion to bring therapies and an improved quality of life to patients around the world, we will only provide solutions that increase speed and efficiency in making available life-changing treatments to the patients we serve.

We build the foundation for success by assembling an elite team for every client, every time. Every team member has a mutual passion and an insatiable desire to share in offering hope and making a difference for the patients we serve during their fight for a better, longer life.

We believe that only teams of functional experts, who share personal attributes of excellence and grit, can deliver transparency, precision, and certainty to an industry that is rife with complexity and disappointment.

