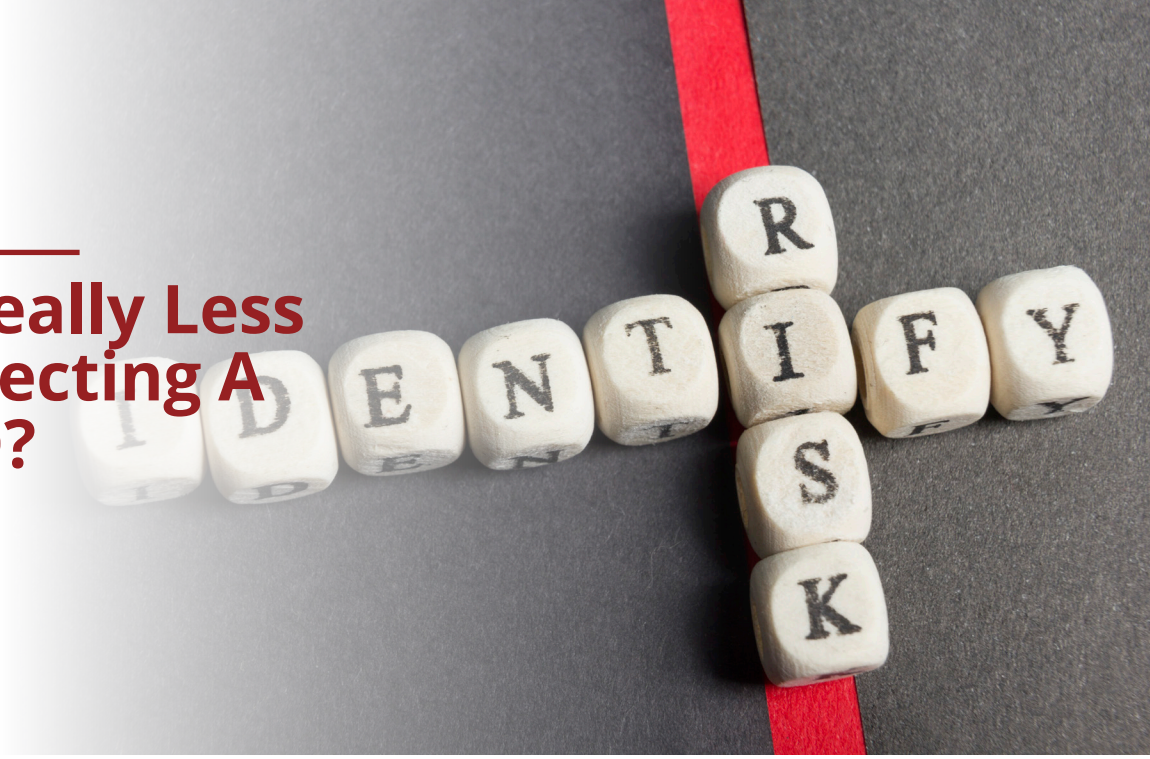
Is There Really Less Risk In Selecting A Large CRO?



Most quantitative and qualitative studies seeking to understand what creates fear and anxiety in humans conclude with some version of the same 4 key criteria: Lack of Control, Large Consequence, Sudden Occurrence, and Unfamiliarity. In our outsourcing industry, it is never an easy decision to select a partner when trying to run complex sequential trials. The need to gain regulatory approval for the treatments you have dedicated yourself to providing, coupled with the need to find a capable, reliable, and fair Contract Research Organization is quite daunting.

- **Lack of Control.** Most companies are highly detail-oriented and have controlled every aspect of getting their therapy up to the point of needing a CRO partner to scale. What control will they keep through this new process and how can they trust these strangers to manage it as they would? These are practically unanswerable questions during a typical vendor evaluation that is often pressed to be completed as soon as possible.
- **Large Consequence.** In clinical trials, each day a drug is delayed in a clinical phase costs the sponsor that much more in future revenue/profit. Though these references are broad and often far from the reality of a particular study, they are printed and stated and promoted to the point that company executives and their investors fully believe that selecting the wrong outsourcing partner could easily result in a disaster in terms of time and/or cost over-runs.
- **Sudden Occurrence** has likely plagued many who have ever managed a study. Sudden occurrences on a human study like serious adverse events, patient access and dropout rates, and overall trial complexity are a daily part of our lives. However, there are certain occurrences that can and should be avoided.

You should never find yourself in a position of coming to the realization that:

- you are getting less than what you expected or were promised
- you will have to spend more time on things you were told other people were doing
- your study has experienced an unexpected loss of key personnel
- you would have been better off doing the work yourself

- **Unfamiliarity** presents itself when having to deal with any of the above concerns, or when you are facing something new – whether you are outsourcing your clinical study for the first time, or searching for a CRO to do a better job than your last one did.

When you consider all 4 of these common drivers of fear and anxiety, it is easy to see how dominant this emotional state likely is for most operational heads entering into the CRO identification, evaluation, and selection process. This is unfortunately why too many decision-makers conclude bigger is better. They falsely believe bigger CROs can build a better team more quickly, can access additional resources (people, money, or partners) as needed, have the experience to pivot quickly when needed, and can ensure each trial moves quickly and efficiently through each step of the process. These opinions are often not validated. The shame is, this "risk avoidance" tendency too often gets in the way of the real work a sponsor should do when selecting a CRO partner, like ensuring each potential CRO demonstrates a detailed understanding of the:

- likely challenges each trial possesses, and even postulates a few options to mitigate if needed
- specific therapeutic area the study is focused on
- importance of dedicating specific professionals in key roles for the entirety of the trial
- regulatory hurdles associated with this specific type of drug

So why might a smaller CRO be better suited to see your study through?

- **Increased therapeutic expertise** – A smaller CRO that specializes in only a few therapeutic areas offers a higher level of expertise within those areas. Approximately 75% of the 500 clinical development outsourcers who participated in Industry Standard Research's 2019 CRO Quality Benchmarking report agreed that small/niche CROs who specialize in only a few therapeutic areas offer a higher level of therapeutic expertise when compared to large CROs.
- **Increased focus** – A small CRO needs studies more than a large CRO, much like an emerging/developing biopharma company needs their submission to be successful more than a large, established biopharma company would. A small CRO's success is fully contingent upon the successful management of a client's study. Again, approximately 75% of the 500 clinical development outsourcers who participated in the aforementioned CRO Quality Benchmarking report said that some CROs are too large, often referencing cumbersome processes and poor communication. When these respondents were pressed for details, they often cited the amount of bureaucracy, poor flexibility, and lack of efficiency as the main reasons.
- **Lack of turnover** – Large CROs have a huge pool of resources; however, this does not mean that they can staff a study quickly. Odds are, their best and brightest people are already engaged with other client deliverables. What they are capable of doing is having the ability to swap team members in and out without much consideration to the impact on the study's efficiency. What if this happened to your study!? This loss

of control makes it difficult to validate that a study is running effectively, and the awful truth is that many in our industry wholeheartedly believe that this is by design - the longer they take, the more you have to pay them. In order to stay competitive, smaller CROs must attract and retain the best talent possible.

The inSeption Group builds teams based not only on technical expertise, but also on passion for the patient. As the person responsible for the overall study management, you will get a full team of people with the technical expertise to make the study successful, and the passion and care to go above and beyond anything you have experienced with traditional CROs. The inSeption Group is a home for clients and professionals who have been stifled by mainstream, high-volume, commoditized outsourcing models. The founders of inSeption Group have witnessed the progressive degradation of today's outsourcing options. Their sole purpose is to challenge today's status quo and eliminate your vulnerability.

THE INSEPTION GROUP – TRIALS RUN YOUR WAY

Based on a deep understanding of you and your target patients, ISG is uniquely capable of building a custom team of specifically experienced professionals passionate about the problems your drugs resolve. These people are independently and collectively capable of conducting even the most complex trials in tight timelines and reasonable budgets.

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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.

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