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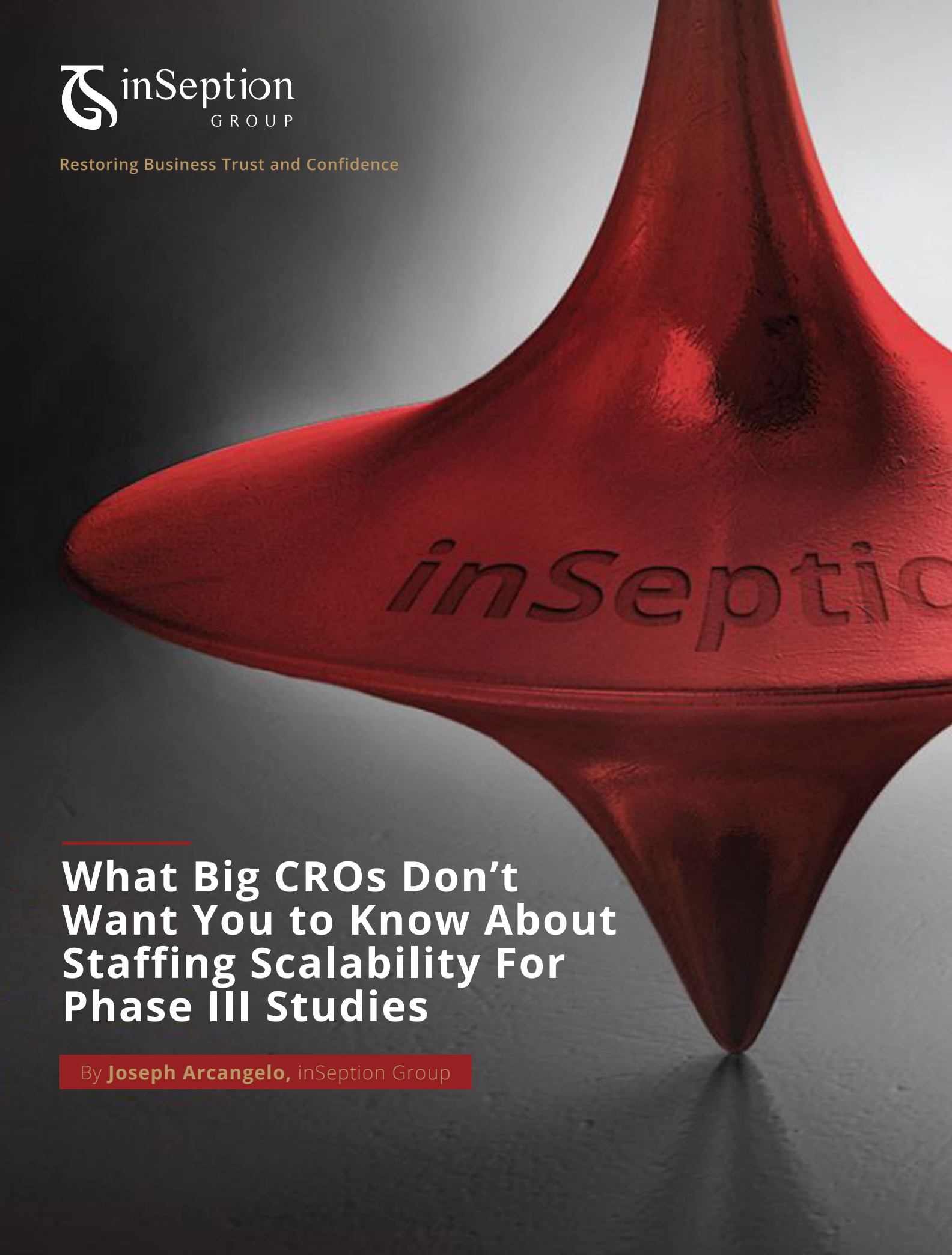

What Big CROs Don't Want You to Know About Staffing Scalability For Phase III Studies

By **Joseph Arcangelo,** inSeption Group

Don’t settle for recycled employees poached from other studies when therapeutically aligned, passionate, and accountable personnel — eager to work on your specific study — are available.

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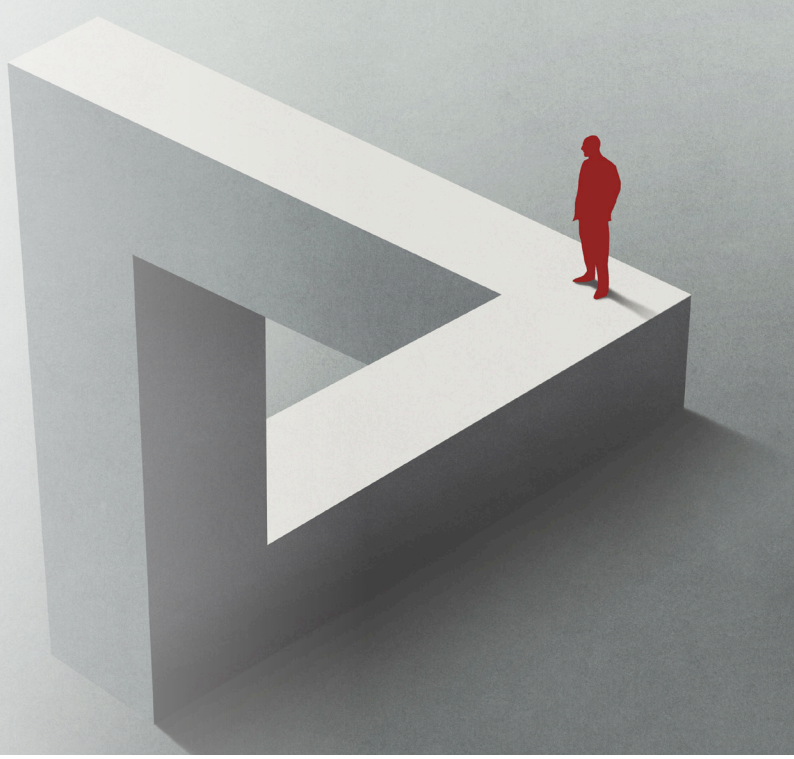

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There seems to be a conventional wisdom stating a Phase III study should be handled by a large CRO. After all, large CROs generally have the resources on-hand to staff such a study within the sponsor's ambitious timeline. In fact, while this model might be advantageous for expansive studies in non-critical indications, it usually fails to meet the personnel needs of sponsors executing Phase III studies in critical indications, ranging from oncology and neurological disorders to development of orphan drugs.

Understanding the pros and cons when deciding between a large CRO and a more niche partner requires an examination of all factors affecting scale up to a Phase III study: therapeutic area, the dynamics of business operations between large and small organizations, how such organizations scale up employee numbers, and more.

WHO IS ASSIGNED TO A PHASE III STUDY, AND HOW?

Regardless of a CRO's size, its static employee base must be engaged in billable work to preserve profitability. This means any given CRO consistently has between 93% and 97% of its employees — if not more — assigned to billable projects. When a sponsor thinks of scalability, they may think, for example, that a CRO with 10,000 employees can draw from the entirety of that talent pool. However, only a fraction of that number generally is available to the marketplace: in this example, 300 to 700 people.

In a perfect world, the individuals assigned to the sponsor's study out of that group are therapeutically aligned with that study and are genuinely interested in advancing science relevant to that

indication. But, the odds are against such serendipity. The sponsor rolls the dice on random employees who may or may not be a good fit for its study. Or, worse, the CRO pulls personnel from existing clients' studies to staff the incoming client's study — an exercise that should make the incoming client wary of when its own personnel will be snatched away for the same reason.

When large CROs need to scale up to meet Phase III study needs, it is common practice in the industry for them to poach employees from other CROs, using promotions, salary increases, or bonuses as bait. This model inhibits the level of talent the CRO is able to attract, since the talent pool remains effectively static. True, the CRO is able to provide personnel, but not necessarily employees who are advantageous to the sponsor's study. This scenario is all but impossible to avoid for a Phase III study in a common, non-critical indication, which may span 100 countries and include more than 1,000 patients. In such a study, the need for quantity usually outweighs the desire for quality (defined here as personnel who are efficient, intuitive, and thrive within collaborative processes).

However, a Phase III study in a critical indication (e.g., orphan/rare disease) requires people who have worked in those disciplines and understand the nuances of that therapeutic area, which is key to creating efficiencies. Non-therapeutically aligned personnel can perform the same job, but sponsors are more likely to encounter errors or delays as these employees learn on the job. In theory, the sponsor's dollars should be paying for expertise capable of completing a job within its qualified timeframe, not footing the bill for training beyond what is necessary to support the protocol.

It also stands to reason a sponsor should be able to vet each employee added to its team by a CRO. But, while the expertise of project managers is heavily scrutinized, sponsors generally do not have insight into the therapeutic expertise of teams working under those individuals. Depending on the size of the study and the indication area, sometimes vetting each employee is unreasonable within the timeframe, or unnecessary.

Critical indications should never fall under this umbrella because the space is very competitive and scientifically oriented, operating at the cutting edge of what is possible. Moreover, patients for such trials often are difficult to recruit, underscoring the importance of "getting it right the first time" at each step of the study. Consider that oncology studies typically do not include large numbers of patients and, sometimes, numerous studies occur simultaneously in the same indication, making it even more difficult to enroll patients.

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Executing a study in such a high-stakes environment and with a relatively small outsourced development team, it makes sense that any sponsor would want to meet and interview incoming employees prior to their assignment/deployment by the CRO. inSeption Group is among a number of outsourced providers to provide this crucial team

member insight ahead of time; with large CROs, you get what they give you. And, as we have noted before, a sponsor may be sold on a large CRO's "A-list" talent at a study's inception, only to have its personnel swapped out during the study because the CRO needs those top people to attract the next client. At that point, the contract is signed and the sponsor has no recourse (at least, no recourse that is not costly and time-consuming).

INTEGRATION + COLLABORATION = SPONSOR CONTROL

Among the most baffling, damaging aspects of traditional CRO operations is their unwillingness to integrate employees with the sponsor's in-house talent. Logic dictates that, during the kick-off meeting between the CRO and the sponsor, the former should evaluate what talent the sponsor has available and whom they need, and then strive to mesh those teams together, encouraging collaboration and efficiency.

Consider the following example of how a CRO keeping the sponsor at arm's length in this way can compromise even a well-run study: an emerging, U.S.-based pharmaceutical company partnered with a large CRO on a cardiovascular study. The company was ready to progress to its NDA submission, which VCs and executives wanted submitted by the end of the year. To facilitate that submission, the company asked its CRO for relevant trial master file (TMF) information. The CRO responded, "We don't have it. We haven't been managing it. We can get it to you by February, but it will cost you an additional fee to do so, since we will need to bring in additional resources." The company chose instead to hire inSeption Group to correct the issue within its executives' and investors' desired timeline.

This example illustrates how some CROs hold companies hostage with their own data as a result of the fallibilities, inconsistencies, or lack of quality service the CRO provided all along. But the company is already millions of dollars into the CRO's pocket and it is under contract. It has no easy solution. This occurs frequently because, to most behemoth CROs, companies like the sponsor in this example are blips on their profitability radar. Accountability is difficult to pin down.

Sponsors working with larger CROs spend significant time chasing, trying to find out what is going on with different aspects of the study, who is handling what — micromanaging. To get those answers, the sponsor is supposed to talk to the CRO project manager. But often, the project manager (if they don't change) doesn't have the answers and the sponsor frequently is not provided access to anyone else on the project.

Presumably, this limitation grants the CRO more precise control of its project, but why is a paying sponsor denied full access to personnel? Transparency fosters accountability. inSeption Group and

many other CROs provide access to whomever the sponsor wants — the project manager, a specific CRA, the company president — by encouraging them to pick up the phone and call. Sponsors have a right to reach anyone associated with their study, at any time, to find whatever information they seek.

A CRO team integrated within the organization it is serving achieves this end. Clear communication and uninhibited collaboration introduce a measure of accountability and personal responsibility. In fact, the best people want to be held accountable for their work. World-class athletes know by heart their statistics and their team's place in the league standings; they want metrics that objectively highlight their talent and capability. World-class drug development experts are cut from the same cloth.

FINAL THOUGHTS

Think again of the fictitious CRO example at the top of this article — the CRO with 10,000 employees, 300 to 700 of whom are available for assignment to your study. That is a viable talent pool but, of those people available, what is their indication experience? Will

they simply be serviceable, or will they be beneficial to my study? The answer is, you don't know until they already are assigned to your study.

Further, if the CRO does not have enough viable candidates to staff a Phase III study, it has to recruit new employees, just like a smaller competitor. How those employees are recruited can significantly impact the study. As a sponsor, do you want a static employee, incentivized by a bonus check or an incremental salary increase, or do you want someone motivated by a passion for the science behind your drug?

Considering such, inSeption exhibits the capability to secure people driven by science who are therapeutically aligned, passionate, and committed to delivering high-quality results. These inSeption resources, fully integrated with a client's operational team, assume personal responsibility to accelerate the pace of development and provide sorely needed innovation, expertise, responsiveness, and accountability to the clinical development process.

Thus, if you need hundreds of people for a global, me-too product study, a large CRO likely is your best option. But, if you need a smaller number of people to staff a study examining a critical indication, maintaining control and eliminating vulnerability are paramount. Demand the same quality of work, the same accountability, from CRO staff as you do your own employees.

To learn more, contact the author or visit us at https://www.inseptiongroup.com/.

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 suboptimal state of the industry today.

Based upon a foundation of character and principle, as well as dedication to the patients, colleagues, and clients we serve, Joe's vision and results-oriented approach have benefited our partnerships and driven their 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.

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