
# Is A Multitherapeutic Contract Research Partner The Best Fit For Your Clinical Trial?

By **Joseph Arcangelo,** inSeption Group

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Restoring Business Trust and Confidence

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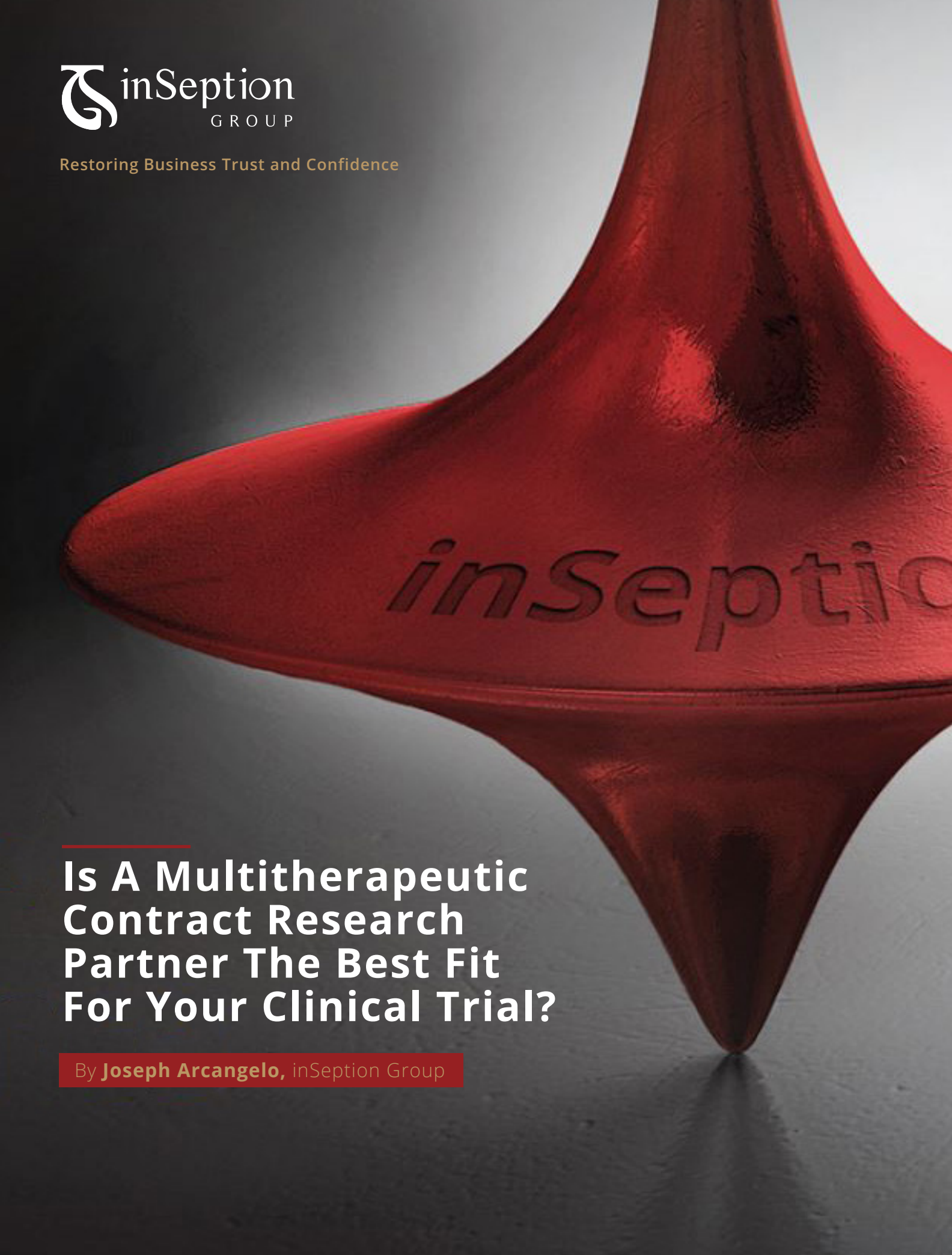


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**You wouldn’t hire a house painter to retouch fine artwork, so why would you contract a jack-of-all-trades research organization to pilot a clinical trial with critical end points that require specific, in-depth expertise?**

# Is A Multitherapeutic Contract Research Partner The Best Fit For Your Clinical Trial?

Many contract research organizations (CROs) tout multitherapeutic capability, claiming they offer clients flexibility and accessibility to vast resources. However, multitherapeutic capability does not always provide the value a sponsor requires. In select instances, a CRO offering multitherapeutic services absolutely is the appropriate partner to run a clinical trial. In some cases, though, partnering with a multitherapeutic CRO can cost a sponsor time, money, and data quality — not to mention frustration and outright aggravation.

## THE GOOD, THE BAD, AND THE UGLY

For sponsors developing a compound or other product intended for (or showing promise across) several therapeutic areas, it is likely advantageous to partner with a research organization that offers a multitherapeutic skillset. The ability of that organization's teams to discuss protocols spanning different therapeutic areas at the site level is enormously beneficial in such cases.

Additionally, studies dealing with non-critical indications — cold- and flu-related issues, traditional vaccines, typical dermatology, etc. — do not require specialized indication expertise and experience. But for sponsors researching products dedicated to critical conditions, like oncology or orphan disease, focused expertise and experience become much more important. These sponsors require outsourced teams fully integrated into their studies, versus an ever-changing cast of team members or personnel not fully dedicated to that specific therapeutic area.

This is not to say multitherapeutic CROs cannot handle such studies. They frequently employ a subset of individuals dedicated to a certain indication or therapeutic area. The CRO attempts to keep people who are indication- or therapeutic-specific assigned to each job but, ultimately, they have to keep their people billable. And to do so, the CRO must assign these individuals where it has need. This gradual (or, in some cases, abrupt) transition from the "A team" initially assigned to a study to the "B team" that may complete the study compromises quality delivery of service.

This transactional approach assigns people to a clinical trial team but it does not always truly integrate them into the study. Many times, the assigned individuals do not fit well with the client's company culture, they are not people whom the client would otherwise have hired, or they are not therapeutically aligned with the study (i.e., they are capable, but their skillset may be lacking).

Sponsors try to insulate themselves against this practice through governance agreements, attaching a KPI to turnover and attrition, and CROs generally agree to these terms when finalizing their contracts. For example, the CRO may attach if/then discounts (e.g., if turnover exceeds 6%, then we'll provide a 3% discount). But the sponsor is likely to spend that 3% — and then some — due to change orders directly resulting from the turnover and attrition. Each change also introduces a delay to the planned study timeline due to the need for additional training.

Depending on the source, turnover in the CRO industry ranges anywhere from 15%-40%. Even the low end of that range is too much; it should be 4% to 9%, at worst. Attrition is tougher to track, but anecdotal evidence is widespread: consider a CRO that has employed an individual for two years, but she has been offered a more desirable position at another company. Her current employer more than likely must promote this person to retain her. In either scenario, the individual is pulled from the three-year study on which she was working after only two years. The client suffers through no fault of their own.

Ultimately, a sponsor has no true recourse to this bait-and-switch. It is too expensive and near impossible from a timeline standpoint to switch outsourcing partners. Adding a second CRO partner is another unpalatable option, as the sponsor now has to manage two service providers, increasing their headaches exponentially.

Once a study is ongoing and outsourced team members begin to change, the sponsor has lost control of the study. Time lost and budget impact are two notable effects of this loss of control, but the loss of intellectual property training is perhaps most damaging. A sponsor working within a very narrow indication, following a protocol written for highly specific inclusion/exclusion criteria, must train each team member on that protocol. Then, that training has to be passed down to each site. When people leave the study, incoming employees must be trained on the protocol to overcome the loss of intellectual property caused by attrition or turnover — over and over. This problem only got worse in the past year as CROs scrambled to assign their best people to COVID-19 vaccine projects (from which Pfizer, Moderna, and Johnson & Johnson — in concert with their partners — emerged with viable solutions out of a field of 100+ competitors).

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Thus, the multitherapeutic claim looks great on paper but boils down to which people will work on a sponsor's study — highly skilled experts, or average resources going where they are assigned — and how long those people will remain part of that study. Sponsors have accepted the impacts of turnover and attrition as an unchangeable state of affairs and have adapted to manage through it. But better options exist to run trials with critical end points.

## WHAT'S IN A NAME?

Sponsors aren't necessarily looking specifically for a multitherapeutic CRO to run their clinical trial; those organizations simply are the easiest partners to identify that can claim the capability to meet the sponsor's needs. Well-known multitherapeutic CROs also offer a perception of minimized risk, both for the study and for the individuals securing the CRO's services.

A popular adage in the personal computer industry once stated, "nobody ever got fired for hiring IBM." The same mindset often guides CRO selection. A larger sponsor may have a few preferred providers, each of whom is sent a request for proposal (RFP). The proposals come back with similar bids and the sponsor chooses one and gets to work. Boards of directors and others involved (e.g., venture capitalists) in the outsourcing decision-making process usually want a well-known CRO. That potential partner may have bid the contract higher than competitors, but they have name recognition. They are hired without much debate, and everybody wins — except the operational teams running the study, who may receive a mixed bag of outsourced personnel and must deal with the budget implications of that uncertainty.

The C-suite and investment community at larger sponsors usually is so far removed from the decision makers that concern for this state of affairs never really reaches that level; the C-suite is more focused on the company's on-the-street and in-the-news appearance. But ask the CMO of a smaller sponsor what it's like reporting change order costs and delays to their CEO and/or board of directors, and "brutal" is a word you'll hear often. They may be used to the way things are partnering with a larger outsourcing organization, but they also have their ear to the ground for a better methodology.

In this respect, numerous alternatives exist to run any given study, but the more decision makers venture outside of traditional CROs, the more they expose themselves. Sure, problems will arise, bringing with them costs and delays, but you don't get fired for hiring a big-name CRO. On the flip side, some of the industry's most gifted researchers have left large outsourcing organizations to start their own niche CROs, companies operating along therapeutic or functional lines aligning with their founders' knowledge. Sponsors simply are wary of smaller outsourcing organizations being able to deliver on their quality promises — despite knowing for a fact larger partners often do not deliver on their claims.

## CONCLUSIONS

Multitherapeutic capability is not inherently a negative. In fact, outsourcing organizations offering expertise across numerous therapies can provide great value for their clients. But a sponsor developing a product with a critical end point (e.g., a novel treatment that can save or enhance lives) benefits by working with a partner that can guarantee therapy and indication-specific employees — not only at the start of a trial, but for its duration. A dedicated group of outsourced employees that exemplifies the qualities a sponsor would seek in its own hires provides value to a study team through depth of knowledge, efficiency, and dedication to the science behind the study.

To learn more about how therapeutic area- and indication-specific outsourced employees can optimize your clinical trial — particularly in critical areas like oncology, orphan disease, and neurological conditions — 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 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.

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