

# Precision Partnerships:

## Your Guide to Selecting the Right CRO

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## Finding the Right Partner

Placing your novel investigational product (IP) in someone else's hands can seem daunting. Still, a trusting partnership between you and your chosen CRO facilitates the best chances for your IP success. When searching for a CRO, there are several factors to consider: What are their project management, staffing, and operations capacities? Can they support you throughout the entire study while maintaining high responsiveness, communication, and flexibility to pivot as needed? It's crucial to view this partnership with confidence, knowing you will have support from start to finish of your trial.

Below, we offer essential insights and guidance to streamline and enhance decision-making processes when selecting a CRO, focusing on sponsor-indicated high-priority factors.

### Communication Is the Foundation of Success





The selection process should begin by understanding communication capabilities and prioritizing a partner that operates with clear and open correspondence. In the early stages of interaction, pay attention to how they listen to and understand your goals. It's vital to gauge whether they approach the relationship as a true partnership or merely as a transactional engagement. A CRO that prioritizes your needs can demonstrate this by ensuring a dedicated team is assigned to your project, minimizing the risk of miscommunication, and facilitating clear, direct, and timely responses. Clear communication also allows the team to quickly pivot when challenges arise and establish procedures to address complications before they escalate.

### Strong Staffing Supports Rigorous Data Collection

The staff should be highly responsive and experienced, with a proven track record of on-time or ahead-of-schedule completion, especially for therapeutic areas that require specialized knowledge and expertise. Moreover, the CRO should have positive interactions and strong relationships with a network of clinical sites, facilitating smoother operations and ensuring rigorous data collection. There should be readily available access to expertise in the therapeutic area and associated nuances. Many clinical assessments need precision to collect accurate, reliable, and valid data, which often requires a dedicated team to teach proper clinical assessment techniques or similar resources to educate the site staff and promote uniform, rigorous data collection.<sup>1</sup> A good staff also supports effective project management, which requires several components moving synchronously to ensure regulatory compliance, efficiency, and ethical trial conduction.

## Well-Executed Project Management Enhances Trial Outcomes

High-quality project management helps to develop a clear initial plan and attends to challenges as they arise. Excellent project management should include resources to confidently demonstrate an active commitment to the following attributes across the organization:

-  Clearly set objectives: specific, achievable, relevant, and time bound
-  Extensive project risk mitigation including early detection and rapid mitigation plans
-  Resource management, including budgeting, personnel, and time
-  Effective communication, engaging all stakeholders, including sites, regulatory authorities, and vendors
-  Clearly defined quality control protocols
-  Strong network of clinical sites
-  User-friendly clinical trial management system
-  Technology for real-time data access 24/7
-  A standardized post-trial protocol (i.e., data analysis, reporting, and regulatory submission)

## Staff Characteristics

In the 2024 ISR Phase II/III Benchmarking Report, Worldwide ranked as the highest-rated service provider for **Project Manager Quality**, outperforming all other Phase II/III CROs in this attribute.<sup>2</sup>



## Operational Excellence & Seamless Service Integration Optimize Resourcing

Operational excellence drives an optimized clinical trial. An ideal CRO should prioritize process optimization and resource management, ensuring precision and efficiency in every trial component. Clearly defined operations avoid excessive vendor management, streamline time and costs, and include in-house medical and scientific professionals who can provide guidance throughout the study. Those with strong operational experience will have well-integrated processes that minimize unnecessary delays and errors, ensuring your trial runs smoothly from beginning to end.



### Service Delivery

Worldwide achieved joint first position for **Operational Excellence** among Phase II/III CROs.<sup>2</sup>



### Core Services

Worldwide was the **highest rated** Phase II/III CRO service provider for **biostatistics**.<sup>2</sup>

## Biostatistics & Data Management Demand Attention to Detail

Attention to detail is paramount in biostatistics and data management. The selected partner should have a dedicated team capable of handling complex data, basing each decision and interpretation on reliable and current information. The infrastructure must support confidential and secure data storage with a user-friendly trial management system that provides real-time data access.<sup>3</sup> It's also necessary that the statisticians are familiar with complex trial designs, such as master protocols when relevant, to increase speed, lower costs, and improve the likelihood of regulatory approval.<sup>4</sup> Improperly collected or interpreted data can severely impact the trial, potentially misrepresenting the intervention's efficacy or endangering participants' health.

## Clinical Trials Require a Global Footprint

Clinical trials are now global, meaning your potential CRO must demonstrate experience with successful multi-regional clinical trials (MRCTs). MRCTs have become especially important in establishing a diverse patient population, particularly for neurodegenerative disorders, oncology, addiction, and cardiometabolic and inflammatory diseases (CVMID), all associated with high patient heterogeneity. Diversity is becoming more crucial for regulatory body approval, as illustrated by the FDA's recent guidance and upcoming requirements for diversity, equity, and inclusion (DEI),<sup>5</sup> as well as the EMA's acknowledgment of its importance. Beyond regulatory factors, the increase in diversity demonstrates a need for cultural sensitivity in protocol design and study conduction. Additionally, it's critical to incorporate regionally and culturally appropriate language in your study to optimize patient recruitment, which plays an indispensable role in MRCTs. Focus on a team that embodies local differences and leads with cultural sensitivity.



### Service Delivery by Geography

Worldwide **outperformed** all other Phase II/III CROs for **Project Delivery** in Europe.<sup>2</sup>

Effective global operations require an in-depth understanding of regulatory bodies, their overlap, and anticipated hurdles and solutions for protocol harmonization. As guidance is often changing, ensure that the prospective CRO maintains up-to-date knowledge of current and planned changes, speaking to how they would impact your design at the outset and during the trial (e.g., updates to patient-reported outcome data requirements as regulatory requirements for oncology trials evolve).

For any company to have sufficient regulatory understanding for protocol harmonization, they must maintain open dialogue with appropriate regulatory bodies and acknowledge the importance of early and ongoing communication during the trial.<sup>6</sup> Regulatory bodies have unique requirements and preferences for tone, depending on the therapeutic area. Having a CRO with familiarity and an active relationship with regulatory bodies will increase the chances of trial approval and avoid unnecessary delays or violations related to misinterpreted feedback.

## Conduct Clinical Trials with Confidence

Developing a novel therapeutic with the intention of either selling or bringing it to market takes time, resources, and thoroughness, which underscores the importance of selecting a partner who applies the same level of diligence. Conduct your trial with confidence by seeking a partner who is agile, responsive, and attentive and who provides clear access to senior-level expertise.<sup>7</sup>

Worldwide is a global CRO currently ranked as a leader in project management quality in Phase II/III trials, based on independent review.<sup>2</sup> We emphasize delivering quality from the outset, providing custom-tailored solutions for each trial's unique needs, and leading with a solutions-forward mentality.

Whether you're planning for an upcoming study or facing challenges in an ongoing trial, such as poor communication or missed milestones, our team is here to provide support and expertise.

The ideal CRO has a network of professionals and sites throughout the world to facilitate:



Saved time and reduced costs



Seamless global access to meet or exceed enrollment



Trial uniformity across sites, regions, and staff

[Contact us](#) today to find out if we're the right fit for your current or next study.

## References

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