

The Right CRO:

Vetting Process for Your Complex Therapeutics



Clinical Research
& Development

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By the Numbers

39%

OF TERMINATED TRIALS WERE STOPPED FOR SLOW ENROLLMENT

10%

OF DRUG DEVELOPMENT FAILURES ARE DUE TO POOR STRATEGIC PLANNING

Clinical research faces a lot of hurdles to completion, ranging from enrollment issues — 39% of terminated trials were stopped for slow enrollment¹ — to poor strategic planning, blamed for 10% of drug development failures.² And as complex rare disease trials continue to grow in number — analysis of clinicaltrials.gov-registered ALS trials shows an increase of 61% from 2018-2021 — these problems are bound to be exacerbated.

With recruitment and retention issues, poor strategy and site and personnel problems leading the pack of challenges clinical trials face, it's hard to deny that finding the right contract research organization (CRO) for your study is of paramount importance. In fact, choosing the wrong partner to manage all the aspects of your trial could derail timelines, budgets and even chances of regulatory approval.

The right CRO, like PRC Clinical, has the expertise to guide your study from start to finish. They know the doctors who know the patients and have the processes in place to achieve success. While not every organization has the skills to give your trial the attention it deserves, here are some tips to find a CRO that does.

6 Characteristics of the Right CRO

- 1. They're nimble.** A big pharma company testing a potential blockbuster may need a large global CRO. For everyone else, an agile CRO that navigates mid-study changes quickly will best serve their needs.
- 2. They get to know you and your trial.** The right CRO will spend time getting to know your company, your project and what makes it unique. You'll meet the CRAs and the CEO, and it won't take long before you feel confident that the CRO is more than capable and understands what it will take to execute your trial successfully.
- 3. They go beyond site access.** Access to high-performing sites is a top benefit of outsourcing to a CRO. However, a large site database does no good if the sites can't enroll patients who meet your inclusion/exclusion criteria. Look for a CRO that prioritizes site selection and activation. PRC Clinical, for example, conducts site qualification visits for each protocol to weed out potentially underperforming sites. During those visits, it reviews databases and asks hard questions to make sure the sites will produce an adequate number of patients, which saves you time and money by ensuring maximum enrollment from as few high-quality sites as possible.
- 4. They provide a solid team.** A CRO's turnover rate isn't important. What is important is the turnover within your study team. PRC Clinical contracts with CRAs and project managers with a minimum of 10 years of industry and therapeutic area experience. These professionals are dedicated to your trial and invested in its success, so they stay with your trial for the life of the project, minimizing disruption.

5. **They let you meet that team in advance.** A CRO staffed with skilled professionals will be proud to show them off. Sponsors should ask to meet their study teams before startup. Early interaction builds relationships, which benefits current and future studies.
6. **They take ownership of the project.** The right CRO takes full responsibility for your trial. They make sure the entire operation runs smoothly, all data are accurate and all milestones are reached according to timeline and budget. They conduct risk-based monitoring and management to anticipate and mitigate risks before they happen. They acknowledge any problems that arise and present solutions.

Choose a CRO That Delivers

When deadlines and budgets are tight, it's tempting to consider managing clinical trials in-house. But remember: A failed trial will cost the company more in the long run than hiring an experienced CRO. As you weigh the options, consider each CRO's proven results and credentials. Choose the CRO that will prioritize your study, react quickly when needed and take the time to get to know your team and your trial. The right CRO will remain transparent when challenges arise and present solutions that allow you to move forward with confidence.

A High-Touch Approach for High-Quality Results

PRC Clinical has broad therapeutic experience and specializes in rare diseases, regenerative medicine, ophthalmology and CNS early-phase trials. Crafting solutions informed by expertise, we provide personalized clinical project management, feasibility assessments and site selection that meet the needs of pharmaceutical, biotech and medical device sponsors. When you partner with PRC Clinical, you reap the benefits of an agile, skilled team that becomes an expert on you and your trial and applies vast knowledge and industry connections to meeting your challenges, including on-time enrollment, ongoing site services and expert document management. When you need superior CRO solutions for your complex and specialized research, PRC Clinical offers unparalleled support.

**When you need specialized handling
for your specialized research**

References

- 1 Williams R, et al. Terminated Trials in the ClinicalTrials.gov Results Database: Evaluation of Availability of Primary Outcome Data and Reasons for Termination. PLOS ONE. Published 2015 May 26;10(5). Accessed 5.19.22.
- 2 Sun D, et al. Why 90% of Clinical Drug Development Fails and How to Improve It? Science Direct. Published 2022 Feb 11. Accessed 5.19.22.

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Therapeutic Expertise



Regenerative Medicine



CNS



Ophthalmology



Pulmonary



Rare & Orphan Disease



About PRC Clinical

PRC Clinical has specialized in providing specialty CRO services for more than 15 years. For biotech and pharmaceutical companies, our innovative approach to executing studies combines high-touch human elements and cutting-edge technology with extensive experience and deep therapeutic knowledge. PRC Clinical has specialized expertise across regenerative medicine, CNS, ophthalmology, pulmonary and COVID-19, rare and orphan disease, and more complex indications. With our host of online management tools, we ensure your trial receives the TLC it deserves from PRC.