



Selecting the Right CRO for your Project

The global contract research organization (CRO) industry is steadily growing. With 1000's of CROs of varying sizes and capabilities, it can be challenging to identify the right service providers for your program. While experienced consultants, referrals from colleagues, and online tools like [ADDF ACCESS](#) and [Science Exchange](#) can help you navigate the CRO landscape, evaluating the core capabilities, reputation, company structure, and staff of any CRO under consideration is critical. Spending time on due diligence upfront can spare you from headaches down the road. Here we provide recommendations for effective due diligence, with a focus on preclinical CROs.

Initial Evaluation

Set up conference calls or online meetings with 3-4 CROs and evaluate the following:

- **Size:** Large, full-service CROs offer a range of services across the multiple stages of the development pipeline. Full-service companies can offer convenience, but will often outsource to subcontracted companies with specific core expertise. Each subcontractor should undergo separate due diligence. Smaller CROs can provide highly specialized techniques and more flexibility, but using this option may require you to simultaneously manage multiple CROs to complete a project.
- **Location:** Consider language and cultural differences, time zones, the need for site visits, and potential issues with material transfers.
- **Company structure:** Research number of years in operation, financial stability, and the training and experience of the technical staff and study directors. Monitor recent company mergers and acquisitions and staff turnover/layoffs to help assess the stability of the company and the staff working on your project.
- **Experience:** Determine the types of sponsors (academic, biotech, or pharma) the CRO most commonly works with. Are they only interested in pharma clients with larger budgets? Assess the company's track record with your disease indication and any previous experience with your drug target. Institutional memory may be a good indicator of a CRO's ability to problem-solve during the study.
- **Level of Expertise:** Identify the CRO's core capabilities. Ask how regularly technical staff perform specialist techniques (e.g. microdialysis). Find out their experience handling certain transgenic animal lines and with particular routes of administration (e.g. oral gavage). Request references and training records for the specific techniques to be contracted. Request validation data, including positive



control data, for all assays and animal models to be used.

- **Accessibility:** Expect timely responses to calls and emails, and enthusiasm for your project. Determine whether the staff is open to regular communication. A flexible and communicative style for both the study director and the technical staff is a must. Evaluate communication style when requesting confidentiality and/or master service agreements.
- **Personal Relationship:** Building personal chemistry and trust with the study director responsible for your project is critical for problem solving and the success of the program. The study director should feel comfortable approaching the sponsor with problems and mistakes that arise during the project.
- **Objective references:** Talk to former clients beyond those suggested by the company and engage third-party consultants to help you select qualified CROs.

Site Visits

Onsite visits are highly recommended for later-stage *in vivo* efficacy studies and IND-enabling work. We recommend meeting face-to-face with the study director and seeking an experienced third-party quality assurance consultant to help facilitate evaluation of study sites for IND-enabling studies. Things to consider at this stage include:

- **Staff behavior:** Observe the professionalism of the staff and assess their level of expertise in their particular domains.
- **Security:** Check that animal cages, reagents, and compounds are coded for study confidentiality. Determine how and where compounds and data are stored and transported.
- **Spot checks:** Request training records for technical staff and check that studies are performed according to the standard operating procedures (SOP).
- **Compliance:** CROs with good laboratory practice (GLP) and good manufacturing practice (GMP) accredited facilities are required for IND-enabling studies. Ask if the company has ever been issued an FDA Form 483 (or Notice of Inspectional Observations) following FDA inspections. This notice is issued when compliance concerns are observed during inspection. For GMP facilities, quality agreements and documentation should also be made available.

Pilot Studies

Pilot studies are generally smaller studies designed to test project feasibility and evaluate communication, data reporting, transparency, and problem solving at an early



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stage. This is one of the best ways to observe CRO capabilities and working relationships.

Final Selection

Cost is a major deciding factor in your final CRO selection, and can vary dramatically by service. Certain assays have standard pricing, but for non-standard and later-stage projects, obtain multiple quotes and discuss proposed budgets, payment schedule, and project milestones. Competitive quotes can help to negotiate pricing, but in the end, you need to strike a balance between cost and the quality of the CRO. Partnering with a reputable CRO you can trust is critical to the success of your project.

References

Lane, R.F., et al. *Optimizing the use of CROs by academia and small companies*. Nat Rev Drug Discovery. 2013, 12: 487-8.