Making the right choice: Essential questions for prospective CROs

A growing number of sponsors are turning to contract research organizations (CROs) to accelerate drug development, optimize resources, and navigate increasingly complex clinical and regulatory environments. However, the full value of a CRO partnership requires more than just outsourcing activities—**it demands strategic collaboration, clear communication, aligned objectives and effective oversight.**

During the request for proposals (RFP) process, it is natural to focus on cost, timelines, therapeutic experience and staffing. These areas matter, especially when teams are balancing budget discipline with pressure to move quickly. But some of the factors that most influence study success—execution risk, decision-making authority, team capacity, transparency, escalation pathways and incentive alignment—can be harder to evaluate from a proposal alone. For sponsors, the challenge is often determining which partner will be transparent about risks, realistic about assumptions and accountable when the study becomes more complex than expected.

Asking the right questions enables you to look beyond a capabilities checklist and better understand how a CRO operates, communicates and responds when things don't go exactly as planned. But knowing which questions to ask can be challenging, particularly when your team is managing multiple priorities and trying to make a high-stakes decision with confidence.

To get the insights you need, use the following questions to guide conversations with potential drug development partners during the RFP or evaluation process.

1 Global project scope

Global studies can introduce country-specific requirements that are difficult to anticipate early. Regulatory pathways, privacy requirements, contract timelines, ethics submissions, import/export considerations, and site activation processes can all affect timelines and costs.

Questions to consider:

- ☐ What country-specific regulatory, privacy, startup or operational risks could affect our timeline?
- ☐ Which activities can be run in parallel, and which must happen consecutively?
- ☐ How do you identify potential country-level delays before they affect study startup?
- ☐ What assumptions are built into the proposed global timeline?
- ☐ Where have you seen sponsors underestimate complexity in studies like ours?

2 Operating model and vendor oversight

The operational model behind a study can be just as important as the science. For lean teams, it is important to understand how the CRO will manage vendors, oversee deliverables, communicate performance and escalate issues.

Questions to consider:

- ☐ Which vendors will be managed by the CRO, and which will remain under sponsor oversight?
- ☐ How will vendor performance be measured, reported and escalated?
- ☐ What level of visibility will we have into vendor milestones, delays and risks?
- ☐ How are budget changes identified and communicated?
- ☐ What governance structure do you recommend for a sponsor with our team size and internal capabilities?

3 Functional challenges

Study success depends on more than protocol execution. Biomarkers, assays, imaging vendors, companion diagnostics, drug supply, central labs or specialized patient identification strategies may need to be ready before enrollment can begin. It is worth clarifying early how the CRO will identify and manage these dependencies.

Questions to consider:

- ☐ What study dependencies could affect startup, enrollment, or data delivery?
- ☐ Which workstreams need to be completed before first patient in?
- ☐ Who owns each dependency, and how will accountability be tracked?
- ☐ How will risks related to assays, biomarkers, diagnostics, drug supply or specialized vendors be managed?
- ☐ What similar dependencies have you managed in recent studies, and what did you learn?

4 Patient burden

Patient burden can have a direct impact on enrollment, retention, timelines, and data quality. Even a strong protocol can become difficult to execute if visits, procedures, travel requirements, or communication expectations create barriers for patients and caregivers. Ask how the CRO will reduce patient and caregiver burden across the full study journey. A thoughtful strategy should reflect the patient population, disease area, geography, site capabilities and realities of participation

Questions to consider:

- ☐ What aspects of the protocol may create the greatest burden for patients or caregivers?
- ☐ How would you recommend reducing burden without compromising scientific objectives?
- ☐ What enrollment or retention challenges have you seen in similar patient populations?
- ☐ How will sites be supported in communicating expectations to patients?
- ☐ What options exist for travel support, reimbursement, remote visits, home health, or other patient-centric solutions?

5 Additional lines of questioning

The best questions are not designed to catch a CRO off guard. They are designed to reveal how your potential partner thinks, communicates, and responds when a study does not go according to plan.

- ☐ **What are the top three reasons studies like ours have missed timelines in the past 24 months?**
  This encourages a more candid conversation about operational realities and reveals whether the CRO understands its own risk patterns.
- ☐ **Can you walk us through a recent study that went off track? What happened, and what has changed in your approach since then?**
  Their answer can reveal how transparent they are about setback and whether lessons learned actually change future execution.
- ☐ **Who can overrule or support the CRO's project manager if major issues arise?**
  Understanding decision authority is critical during enrollment delays, protocol amendments, vendor issues or budget concerns.
- ☐ **How many studies is the proposed project manager currently supporting?**
  A senior title matters less if the person doesn't have the bandwidth to stay close to your study.
- ☐ **What percentage of the proposed team is currently allocated to other studies?**
  This can help you understand whether the team has the capacity for your program needs.
- ☐ **What turnover rates have you experienced in this therapeutic area over the past year?**
  Staff continuity can have a meaningful impact on study execution, site relationships, institutional knowledge, and overall momentum. It's often a bigger predictor of success than CRO size.
- ☐ **Choosing a partner, not just a provider.**

Choosing a drug development partner requires understanding how a team will make decisions, communicate risks, protect your timelines, and stay accountable when challenges arise.

For sponsors, especially those operating with lean teams and high-stakes milestones, asking probing questions early creates a partnership built on transparency, shared ownership and confidence in execution. **By choosing the partner best equipped to advance your program, you ultimately support better outcomes for patients.**

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