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How to Choose a CRO, the Most Important Decision in a Clinical Study

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If you are going to hire a contract research organization (CRO) to conduct your study, it is essential to find one that will do the job right. If you have made wise CRO-selection decisions in the past, you might be able to just continue on with them. However, if you need to find a new CRO, you should make the same commitment to your selection process that you expect the CRO to make to your study.

Deciding Exactly What You Need

The first step is to decide what you want from, and in, a CRO. The second step is to identify a list of CROs to contact. The third step is to select the one CRO that best meets your needs.

Once you fully understand your needs, create a list of three to eight CROs to go through the selection process. Ask colleagues, professional contacts, key opinion leaders (KOLs), and clinical research sites for recommendations. Try to find out which CROs are most active in your area of need. Send out a request for information (RFI), as needed, to create and refine your list.

You will make your selection based on numerous criteria. Key areas of focus should be:

- **Study phase.** Different types of studies — feasibility/proof of concept (POC), pivotal, post-marketing, etc. — have different requirements. With a feasibility study, for example, what experience does the CRO have with this type of study? Is it nimble enough, both from a costing and operational perspective, to accommodate the often-fluid needs of a feasibility study? You might assume that small CROs are best suited for small feasibility studies, but some large CROs have groups that specialize in them. In contrast, with pivotal studies, a CRO with robust infrastructure, processes and quality systems is needed to maximize data quality and subsequent timely regulatory submission and approval.
- **Geography.** If you might want to conduct your study across multiple geographies, consider each CRO's strategy for covering each country or region. Do they have local offices — "feet on the ground" — in each geography, or do they rely on local partners? In many developing countries, personal relationships can be very important for obtaining timely approval. It is critical to understand the CRO's global infrastructure and coverage strategy and whether that model is most appropriate for your program.
- **Therapeutic expertise.** Your CRO will, of course, need therapeutic expertise, but that can mean different things for different studies. How much experience is required, and in how close a therapeutic area? Does every team member need deep expertise? Is that experience needed at the corporate level, or is your project team's expertise enough? And finally, what about device studies — does the CRO need deep experience in device studies, or can your team provide that? All of these are important questions to answer.
- **A CRO that grows with you.** Clinical development of a product requires a series of studies. In addition, you might be planning to develop multiple products across multiple therapeutic areas. What is your attitude about short-term vs. long-term tradeoffs? A small, specialized CRO might be ideal for your first feasibility study, but can it carry you all the way through to regulatory approval and beyond? You might, instead, want to

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start now with a larger, process-heavy CRO and build a relationship that will pay off in later phases. There might also be a better cultural fit with a CRO of similar size to your company.

The Request for Proposal (RFP) Process

Once you have your list of potential CROs, send them a request for proposal (RFP). RFPs can range from a single paragraph in an email to a 10-page package with detailed instructions and forms. Ideally, your RFP should include the following elements:

- **Expectations.** Describe what information you want, in what form you want it, and when you want it. (Most CROs require two weeks to respond.) In some scenarios, you will require only a budget, but you will usually want a comprehensive proposal including study team members, country and site recommendations, risks, etc. A CRO's detailed response to this request will provide data for the "soft measures" discussed below.
- **Study specifications.** The CROs will need grist for their mills. They will want to see a list of required services and your thinking on eligibility criteria, enrollment rate, schedule of events, special procedures and assessments, and other elements of the protocol, timelines, geography, etc. The more detailed and structured your specifications document, the better you will be able to compare cost and delivery models across CROs. However, by leaving some of these items out in the first pass, you can learn more about the CROs' thinking. For example, asking them to provide protocol comments, monitoring strategy, and/or a list of potential sites will give hints as to how well they understand the therapy and disease state. In a second pass, you can adjust and fill in details based on what you learned in the first pass.
- **Budget grid.** Every CRO has its own budget grid cost "buckets" and format, so it can be hard to compare costs across CROs. If you want them to use your budget grid, make sure they will be able to understand and use it.

Review Process

Now that you have collected information from all the contending CROs, you can start your analysis and narrow the field to a small number of finalists.

- **Delivery model.** While it is tempting to look at the budget numbers first, they can be very misleading until you understand the delivery models. Therefore, first thoroughly understand what each CRO is delivering and how it plans to deliver it. Focus on the startup timeline, enrollment rates, monitoring strategy, statistics strategy, and the full-time equivalents being assigned to the study. Carefully review the timeline, especially the start-up timeline and proposed enrollment rates, if you didn't provide them. The CROs should have provided objective information supporting the enrollment rate and site start-up duration in each geography.
- **Budget numbers.** Reviewing and comparing budget numbers can be very time consuming, not to say frustrating. In a full-scope project, there can be millions of dollars spread across dozens of line items. If you did not provide a budget grid, try to bucket related direct costs together to compare across CROs. The largest buckets might include project management, data management, monitoring, safety and biostatistics. Make sure you understand whether each CRO is proposing a unit based, milestone based, or time and material budget. (A quick word on pass-throughs costs, such as database hosting, investigator grants and travel: While these are all very important, you might want to focus on direct costs only at this stage and later revisit pass-through costs after you've narrowed the field down to the finalists.)

- **Soft measures.** While the formal proposal review typically starts when the CROs deliver their responses to your RFP, the assessment process actually starts well before, with your initial contact, and continues until a contract is signed. How responsive was the CRO? Did it intuitively understand the study's goals? How thoughtful were its questions, and did they proactively provide resolutions to questions? Was it well organized? Were the interpersonal interactions smooth and natural? Did the CRO ask intelligent therapeutic- and study-specific questions? Did it provide useful answers to your questions? Did it make insightful comments about the study? Did its proposal look tailored to your needs or just boilerplate? Did it bring its "A Team"? And perhaps most importantly, does your gut say you can rely on the CRO to work actively and collaboratively to achieve your goals?

Bid Defense

In the bid defense phase, you invite each finalist to an in-person meeting in which they explain their proposal, answer your questions, and ask some of their own, to make sure both parties fully understand the assumptions about and expectations for the study.

Occasionally, study sponsors will forgo the bid defense phase or do the meetings by telephone or online. This is a bad idea — skipping in-person bid defense meetings is like not interviewing the final candidates for an executive position. There is no substitute for a face-to-face assessment of organizational culture, approaches to problem solving, who the key players really are, the interpersonal chemistry of the prospective combined team, and whether the proposed team has actually been engaged in the process. In addition, in-depth discussions of potential issues are more likely to occur in a face-to-face meeting.

Either the sponsor or the CRO (or both together) can set the agenda for a bid defense meeting. If the sponsor sets the agenda, it can focus the meeting on the topics of most interest, i.e., those most important to the success of the study and those that will best differentiate the CROs. If the CRO sets the agenda, each CRO will demonstrate what it thinks are the most important topics and how it will approach the study.

With either approach, look for presentations that are not just the CRO's standard pitch but are customized to your study. A good bid defense will demonstrate that the CRO provides an expertise your team does not have and has given a lot of thought to your study. A good meeting will probably surface issues that had not already occurred to your team and evolve into more of a discussion than a presentation.

Bring key members of your project team to the meeting. Insist that the CRO brings key members of its proposed project team, rather than executives representing each functional area. That way, you can assess whether your people and their people will work together smoothly.

Final Selection

Following the bid defenses, the choice of CRO might seem obvious to you, but, before making a final decision, regroup as a team and discuss each CRO. Use a score card to structure the discussion. To the extent possible, involve and obtain buy-in from all stakeholders.

Once you have made your decision, commit to it fully. Be realistic in your expectations. There will be bumps in the road that the combined study team will have to work through together. If all goes well, the two organizations will build a strong relationship that carry over to future studies.

Other Considerations

Keep in mind that, when you hire a CRO, you are betting on both the study team and the CRO as a whole.

While you are evaluating the CROs, they are also evaluating you. They have to decide where to allocate their resources. The last thing they want to do is get themselves into a frustrating and unrewarding project. Remember that the project team will include members from both companies, ideally with full transparency and information sharing.

In addition to evaluating the CRO's team, you should be evaluating your own team. Where are the gaps in your expertise? Are there any aspects of your science, policies, processes or culture that the CROs need to understand?

As a final note, remember that past results are no guarantee of future performance — there are just too many variables. Every study is different, people change, and the world changes. In other words, look at each CRO outsourcing decision with fresh eyes, and go through the process diligently every time.

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