

# DO NOT OVERLOOK THESE ISSUES BEFORE YOU SELECT A CRO

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The selection of an appropriate contract research organization (CRO) is tantamount to the success of your clinical study. It is a complicated process with many pitfalls you need to avoid. The following is a brief discussion of important topics that may be overlooked in the selection process. There are diverse CROs with different types, sizes, and specialties to choose from. It may initially be tempting to go with a large full service CRO (that offers clinical, regulatory, data management, statistics, and other capabilities). However, it is most important to find the CRO that can deliver the highest quality clinical data on your behalf. It may not be necessary to use a multinational company if you are only conducting a domestic study. The key is to select a CRO that is truly dedicated to providing an excellent study, on time, on budget, with cleanest possible data. They need to keep the investigative sites very engaged on your project. This CRO should provide you with clear, concise, regularly scheduled communication, so that you know everything that is happening with your project. The only surprise that you should encounter is that they are ahead of schedule. Your personal chemistry, faith, and trust in the CRO's staff that is running the trial is crucial to its success. The following tables provide key points to consider in your selection process. The sections in Table I really are important for each other but may be of more significance for a regulatory versus post marketing study, depending on the reason for the clinical trial. Table II serves as a reminder to carefully check the claims that the CRO may assert to ensure that if it fits your company's needs and current situation.

- **TABLE I. KEY ELEMENTS TO LOOK FOR IN YOUR CRO SELECTION**  
~~is the Project Manager's experience in your therapeutic area.~~

**Registry Studies**

- Are senior monitors assigned to the trial?
- Does the Medical Monitor understand your product?
- Is the CRO team truly engaged in the project?
- Will the team ensure accurate recordings of adverse and serious adverse events?
- Is the CRO's culture compatible with yours?
- Does the CRO have positive recommendations?
- What is the CRO's turnover at critical positions.
- What is the CRO's proposed frequency of scheduled communication?
- Is the Medical Monitor a safety and pharmacovigilance expert?

### **Post Marketing Trials**

- Do you sense the right chemistry between the CRO, your team and the investigator sites?
- Does the CRO provide great customer service?
- Does the CRO understand the reasons for this clinical trial?
- Can the CRO engage the investigator and the site's staff?
- Will the CRO be able to work well with inexperienced investigators?
- Are the CRO's enrollment projections realistic?
- Will the CRO stimulate and encourage site enrollment?
- Is the CRO able to educate and train the investigative site?
- Can the CRO act like an extension of your team?
- Will the CRO help provide a smooth transition after the study has ended?

### **TABLE II VOID THESE PITFALLS IN YOUR CRO SELECTION**

- | <b><u>CRO ADVERTISEMENT</u></b>   | <b><u>WHAT IS REALITY?</u></b>  |
|---|---|
| <ul style="list-style-type: none"> <li>• “Our CRO has completed the most studies in indication</li> </ul> | <ul style="list-style-type: none"> <li>• <i>This is no guarantee that this staff is assigned to your project</i></li> </ul> |

- We offer ‘one stop shopping’ and provide all the services that you need
- All our CRAs are certified
- The FDA respects our work
- We may be more expensive but you get better quality
- Our budgets are very specific
- We have the most experienced staff
- We work with the top KOLs
- This does not mean that each of the services are of the same quality
- *This does not guarantee quality*
- *FDA respects quality data*
- *Expensive charges are not correlated with quality results*
- *Will this generate large out of scope fees?*
- *Will you get the “A” or “B” team? And will they be switched?*
- *But what is your assigned team’s relationship to KOLs?*

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