Things to Consider When Selecting a CRO

Evaluating a Contract Research Organization (CRO) for your clinical project may seem like a daunting task. You may begin with the internal assessment of the research project(s) to determine which activities may be done in-house and which will be outsourced. Then, there is the need to identify a manageable number of appropriately experienced CROs to request proposals. Finally, CRO capabilities and proposals must be compared to assess the most appropriate partner for your project.

CRO options range from large, publicly owned companies with comprehensive services and global coverage to privately-owned niche providers with specialized services. CRO services and budgets often vary significantly with respect to details and assumptions, which makes comparisons difficult. And, the CRO employees you talk with or meet may not be the ones assigned to your project.

To facilitate an efficient, effective evaluation of CROs, Promedica International (PMI) has compiled the following suggestions for your consideration.

Services Provided
It seems obvious that you would only consider CROs offering the services you need. However, don't accept things at face value – check to confirm mutual understanding of the activities included in each service, as well as any applicable geographical considerations. Check, also, if the CRO's services are all provided by CRO employees/subsidiaries, or via alliances with niche service providers – having everything "under one roof" may facilitate project management, but niche service providers often outperform a large CRO in their designated area of expertise.

You might also ask for and consider the CRO's suggestions regarding services that may facilitate more efficient completion of your project.

Related Experience – Similar Projects
Related project experience at the CRO often translates into program efficiencies for you – in procedures, work templates, resource networking, and team training. If the CRO does not have directly related project experience, you might ask for metrics regarding other projects that may be similar in terms of trial design, subject demographics, and medical practice patterns.

Related Experience – Similar Clients
Sponsor companies have a variety of organizational cultures and structures. Early stage companies often have a singular focus on the status of their trial and the need to know details regarding trial activities at any given time – they typically want a fast response and creative problem-solving.

Established companies may delegate the trial and request only periodic status reports – they may place a higher priority on procedural rigor than speedy response. What is your company's culture? Does this CRO have experience working with companies similar to yours?
Financial Stability
The CRO business involves significant business risk; e.g., regulatory approvals may be delayed, products may not be sufficiently efficacious to proceed to the next study phase, and sponsors sometimes change business strategies that may result in project cancellations. You want to feel comfortable that the CRO is financially strong enough to withstand business downturns while providing appropriate attention to your project.

How long has the CRO been in business? Is their project portfolio sufficiently diversified to mitigate the risks described above? What practices does the CRO utilize to facilitate sound cash flow management?

Employee Training, Experience, and Stability
What are the educational and professional backgrounds of the CRO’s employees? Do they have sufficient experience and training in Good Clinical Practice to perform assigned project tasks effectively?

Also, project team turnover generates additional expense and inefficiency. What metrics can the CRO provide regarding employee retention?

Delivery of Services
“How does a project get to be a year behind schedule? – One day at a time.”1 Take time to understand how the CRO delivers their services and evaluate how their systems will integrate into those of your company.

Who at the CRO is responsible for managing the project schedule and budget? Who supervises the project team? Who at the CRO is ultimately responsible for your project? Did you have a chance to meet and talk with the key person(s) who would be working on your project? Generally, a single point of contact facilitates clearer communication.

How detailed is the project budget provided by the CRO? Did they take sufficient time to review the budget so that you can verify concurrence of assumptions and general plans? How often does the CRO invoice and how well does the invoice format match the budget provided? What sort of budget reports can the CRO provide?

What is the CRO’s typical format for reporting and monitoring on the project schedule? Does the CRO have a comprehensive checklist of tasks required for clinical trials?

1Fred Brooks, Software Engineer and Author

Track Record – Budget/Schedule
Because of the uncertainties associated with conducting human clinical trials, many project budgets and schedules may be revised once or more after project initiation. How does the CRO handle this? Are they proactive in identifying and addressing deviations? You may want to get the names of client references you can talk with to get additional data about the CRO’s performance this area.

Track Record - Client Satisfaction
Client satisfaction is important data for evaluation of the CRO’s performance; however, be careful not to base your entire assessment on feedback from only one client. Does the CRO have a formal method for monitoring client satisfaction across projects? If so, how often is this assessed and what metrics can the CRO provide? Again, you may want to get the names of client references you can talk with to get additional feedback about their experience working with this CRO.
Infrastructure
Appropriate CRO infrastructure is essential to support your project requirements.

Does the CRO have adequate facilities and staff to handle your project requirements?
What software is used to track project performance?
How is the clinical information system organized? - Is clinical data maintained in accordance with 21 CFR Part 11? What steps must be taken to export data maintained at the CRO into your company’s system?
What mechanism does the CRO provide to facilitate sponsor review of clinical study data?
How does the CRO manage essential study documentation?

Quality Assurance
Quality assurance is essential to good clinical research practices. Decisions regarding product safety and efficacy are based on the assumption of study integrity.

What methods does the CRO use to implement their services and confirm the quality of their work?
What experience does the CRO have with FDA or other applicable regulatory authorities? Have they been audited by any of these authorities? If so, what was the result? If observations were noted, what has the CRO done to address these observations?
Does the CRO have any additional quality assurance credentials; e.g., ISO certification?

For more information, please contact:
Promedica International
3100 Bristol Street, Suite 250
Costa Mesa, CA 92626
Phone 714-460-7363, Fax 714-460-7364
www.promedica-intl.com
CRO Evaluation Checklist

1. Does the CRO provide the services necessary for your project? Are the services provided by CRO employees/subsidiaries or via alliances with niche providers?

   - Project management
   - Protocol development
   - Investigator meetings
   - Patient recruitment
   - Study monitoring & site management (consider geographical location of study sites)
   - Data management
   - Biostatistics
   - Clinical study report or manuscript preparation
   - Test product inventory management
   - Other

2. What is the CRO’s experience with similar projects?
   Services provided?

   Relevant metrics?

3. What is the CRO’s experience with similar clients?
   Services provided?

   Relevant metrics?

4. How long as the CRO been in business?

5. What is the CRO ownership structure?

6. What is a typical project portfolio (number & types of projects) for the CRO?
7. How does the CRO manage cash flow?

8. What is the training and experience of the CRO employees and consultants?
   What is the background of key management employees?
   
   What is the CRO training program for new employees?
   
   What is the evaluation process for contracted consultants?
   
   What is the CRO training program for contracted consultants?
   
   Does the CRO maintain and share metrics regarding employee retention?

9. How does CRO deliver their services?
   Does the CRO use a comprehensive checklist of tasks required for clinical trials?
   
   Who supervises the project team?
   
   What position at the CRO would ultimately be responsible for our project?
   
   What is the format of the project schedule?
   
   Who at the CRO is responsible for managing the project schedule?
   
   What standard schedule management reports can CRO provide?
   
   What is the format of the project budget?
   
   What is the CRO’s invoicing procedure? How does invoice format compare vs. the budget provided?
   
   Who at the CRO is responsible for managing project budget?
   
   What standard budget management reports can the CRO provide?

10. What is the CRO’s procedure for handling budget or schedule changes?
11. Does the CRO maintain and share metrics regarding client satisfaction?

12. Will the CRO provide a list of clients for you to contract regarding their services?

13. Infrastructure
   Does the CRO have adequate facilities and staff to handle project requirements?
   What software is used to track project budget and schedule performance?
   What software does the CRO use to manage clinical study data?
   Is the CRO clinical study data management software in compliance with 21 CFR Part 11?
   Will the CRO's data management software/system facilitate efficient data exports/reviews by outside sources (e.g., biostatistician, medical monitor, etc.)?
   How does CRO track and manage essential study documents?

14. Quality Assurance
   What methods does the CRO use to establish and confirm the quality of their work?
   What experience does CRO have with applicable regulatory authorities?
   Has CRO been audited by applicable regulatory authorities? If so, what was the outcome?
   What quality assurance credentials does CRO possess?