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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 specializing in particular therapeutic areas. CRO services and budgets often vary significantly with respect to details and assumptions, which makes comparisons difficult.

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

SERVICES PROVIDED

Confirm mutual understanding with the CRO regarding the activities included in each service, as well as any applicable geographical considerations. Check, also, if the CRO's services are provided by their employees/subsidiaries, or via alliances with niche service providers – having everything "under one roof" may facilitate project management, but niche service providers often outperform large CROs in their designated area of expertise.

You might also ask for 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 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 proactive planning, a fast response and creative problem-solving.

Established companies may delegate the trial and manage via periodic status reports and meetings – 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

CROs typically operate with significant business risk because their work involves new products that may not ultimately be developed and commercialized. Projects may be cancelled for any number of reasons and you want to feel confident that the CRO you select has sufficient financial strength to withstand these situations without negative impact to your project. You should ask how long the CRO has been in business. Is their project portfolio sufficiently diversified to mitigate the risks described above?

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

Take time to understand how the CRO delivers their services and evaluate how their systems will integrate into those of your company.

Who are the CRO team members who will work on your project, what are their responsibilities and who at the CRO is ultimately responsible for your project? Will that person be your primary point of contact? What is the planned communication schedule between the CRO and your company?

Does the CRO have a comprehensive checklist of tasks required for clinical trials? Have you had a chance to meet and talk with the key person(s) who would be working on your project to verify assumptions and general plans? What monitoring and tracking reports can the CRO provide?

TRACK RECORD – BUDGET/SCHEDULE

"How does a project get to be a year behind schedule? One day at a time."[1] Because of the uncertainties associated with conducting human clinical trials, project budgets and schedules may be revised after project initiation. How does the CRO handle this? Are they proactive in identifying and addressing deviations? You may want to request and interview client references to get additional data about the CRO's performance in this area.

[1]Fred Brooks, Software Engineer and Author

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 request and interview client references 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?

Giving careful consideration to these issues and preparing a checklist relevant to your program needs before initiating the review process will streamline your evaluation of prospective CROs. This should increase your confidence that the CRO you select will be well suited for your project.