

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
- Regulatory affairs
- Protocol development
- Investigator meetings
- Patient recruitment
- Study monitoring & site management
(consider geographical location of study sites)
- Safety monitoring
- 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 has the CRO been in business?

5. What is the CRO ownership structure?

6. What evidence can the CRO provide with respect to their financials?

7. 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?

8. How does the 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 the 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?

9. What is the CRO's procedure for handling budget or schedule changes?

10. Does the CRO maintain and share metrics regarding client satisfaction?

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

12. 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 the CRO track and manage essential study documents?

13. Quality Assurance

What methods does the CRO use to establish and confirm the quality of their work?

What experience does the CRO have with applicable regulatory authorities?

Has the CRO been audited by applicable regulatory authorities? If so, what was the outcome?

What quality assurance credentials does the CRO possess?