*This information should not be considered to represent advice or guidance on behalf of the U.S. Department of Health and Human Services or any agency or office thereof.*

# An Innovator's Guide for Evaluating a CRO in Clinical Research

## Context

Selecting a Clinical Research Organization (CRO) for developing drugs, devices, or vaccines requires a comprehensive evaluation of the organization's capabilities, reliability, and track record. Conducting site visits and engaging with the CRO's team offers valuable insights into their operational practices and culture. Such in-depth assessments are vital to determine a CRO's fitness for clinical development projects, especially regarding regulatory filings through Phase I-III clinical trials for drugs, devices, and vaccines.

## Checklist

While prioritizing due diligence criteria for selecting a CRO is inherently subjective and will vary based on the product's unique needs, a basic hierarchy can be proposed, emphasizing the importance of each element in the due diligence process. This ensures the successful conduct and regulatory compliance of the clinical trials.

1. End-to-End Service Capability

☐ Do you offer a full slate of comprehensive services (e.g., from preclinical stages to Phase III and regulatory submission support)?

2. Experience and Expertise

☐ What experience do you have with clinical trials within our product's specific therapeutic area?
☐ How much experience do you have in managing clinical research?
☐ Do you have any case studies or references from projects similar to ours?

3. Staff Qualifications and Training

☐ What information can you provide on staff qualifications? Can you show GCP competency?

4. Past Performance and References

☐ Do you have references available?
☐ Have you had any prematurely terminated trials?

5. Financial Stability and Transparency

☐ What evidence can you provide to demonstrate the financial stability of your organization?
☐ What is your fee structure? Can you provide an overall cost estimate?

6. Project Management

☐ What is your strategy/process for managing clinical trials?
☐ What processes are in place to ensure you meet timelines and milestones?

- ☐ What types of project management tools or software do you use?

7. Risk Management
   - ☐ What risk management strategies do you have in place? How have you responded to unexpected trial challenges in the past?

8. Vendor and Third-Party Management
   - ☐ What are your processes for selecting and overseeing vendors and third-party services?

9. Patient Recruitment and Retention
   - ☐ What strategies are used for patient recruitment? How do you ensure demographic diversity?
   - ☐ What is your success rate in achieving enrollment targets?

10. Safety Monitoring
    - ☐ What is your process for monitoring and reporting adverse events?
    - ☐ What safety surveillance mechanisms do you have in place?

11. Facilities and Technology
    - ☐ What resources are dedicated to clinical trial management?
    - ☐ How do you manage investigational products?

12. Communication and Reporting
    - ☐ How often do you provide progress reports and what format are they in?
    - ☐ What is your communication protocol with clients?

13. Intellectual Property and Confidentiality
    - ☐ What measures do you have in place to protect intellectual property and ensure confidentiality?

14. Regulatory Knowledge
    - ☐ How do you stay informed of regulatory changes in different clinical trial jurisdictions?
    - ☐ How have you resolved regulatory compliance issues in the past?

15. Quality Assurance
    - ☐ What quality assurance framework do you use?
    - ☐ How is data integrity preserved?
    - ☐ What standard operating procedures do you have in place for clinical trial inspection?

16. Audit and Inspection History
    - ☐ Have you had audits in the past? Can you share previous audit and inspection reports?
    - ☐ How do you plan for and respond to regulatory audits?

17. Interactions with Regulatory Bodies
    - ☐ How often have you met with FDA and/or EMA? What strategies/processes do you have in place for responding to their inquiries?

18. Regulatory Filings and Documentation
- ☐ What experience do you have with regulatory filings for different types of medical products?
- ☐ What processes are in place to ensure the thoroughness of all regulatory documentation?
- ☐ What is your process for Clinical Study Report (CSR) development?

19. Data Management for Regulatory Submission
- ☐ What are your data management practices and do they comply with the regulatory standards for data submission?

20. Experience with Phase-Specific Trials
- ☐ What experiences do you have with Phase I, Phase II, and Phase III clinical trials?
- ☐ What issues or problems have you encountered progressing through the phases?

21. Global Trial Experience
- ☐ Do you have experience managing global clinical trials? Do you have expertise in international regulations for clinical trials?

22. Efficacy and Safety Data Presentation
- ☐ How do you typically present safety and efficacy data to regulators?

23. Market Approval Process
- ☐ Can you provide examples of previous involvement in the market approval transition?

24. Federal Research Compliance
- ☐ What processes do you have in place to ensure compliance for federally funded research?

This checklist is a general guideline and should be customized according to the specific criteria and priorities of your clinical development projects. Assessing each aspect considering the study's unique requirements and your expectations is crucial.