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Hiring A Contract Research Organization?

20 QUESTIONS TO ASK FIRST

Hiring the right contract research organization (CRO) is an important step in conducting a successful medical device trial. You need a CRO that is large enough and experienced enough to meet your needs, but not so large that you feel like just a number. Here are 20 essential questions to ask as you evaluate your options.

DO THEIR SERVICES MEET OUR NEEDS?

1. Can they provide consulting support before your trial begins?
2. Do they have full-service capabilities to provide ongoing support throughout the trial?
3. Will they assist with study closeout and data lock after your trial has ended?

DO THEY HAVE ADEQUATE TRAINING?

4. Does your CRO have a strong regulatory basis for making decisions in the clinical research setting—including deep knowledge of FDA regulations?
5. What is their process for training their own staff and yours to understand and follow those regulations?

DO THEY HAVE A GLOBAL REACH?

6. Do they have experience working with global medical device studies?
7. Do they have global partnerships, such as relationships with monitors abroad?

CAN THEY EFFECTIVELY MANAGE BUDGETS?

13. Do they bill their services on an hourly basis or as part of a monthly retainer?
14. How do they address potential changes to the scope of the project that could impact the budget?

DO THEY HAVE A PROVEN TRACK RECORD WITH MEDICAL DEVICES?

8. What are their areas of therapeutic expertise?
9. Have they worked primarily with medical device studies?
10. What is the track record of the studies and sites they've worked with in the past?
11. Have any of their sites received warning letters from the FDA?
12. Can they provide specific case studies?

ARE THEY THE RIGHT SIZE AND THE RIGHT FIT?

15. How would they describe their company culture?
16. Will the management team remain involved in your trial?
17. What are the retention rates of their team?
18. How will they ensure there is an adequate transfer of information if someone on the team leaves?
19. Do they have the flexibility to offer additional support if needed?
20. How will they communicate with your team?