JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 4, No. 1, January 2008 "Can You Handle the Truth?"

Should You Be a Clinical Research Principal Investigator?

By Norman M. Goldfarb

Becoming a principal investigator is a significant undertaking. Only a small fraction of investigators – about one in seven – conducts over four studies. To find out if you are likely to be a successful principal investigator, answer the following 21 questions. Any "no" answer should give you pause.

1. Do you have access to an experienced investigator or study coordinator to help you answer these questions?
2. Do you have first-hand experience with a clinical trial?
3. Have you spent over four hours reading about the operational and regulatory aspects of clinical research?
4. Are you prepared to make a serious commitment to clinical research, i.e., not just as a hobby?
5. Are you comfortable enrolling your patients in double-blind, randomized, placebo-controlled clinical trials?
6. Are you willing to conduct trials knowing that almost half of drugs that enter Phase III clinical trials do not obtain FDA approval for marketing?
7. Are you willing to accept risks such as serious adverse events, erratic revenue and profits, and FDA sanctions?
8. Are you willing to study clinical research (e.g., GCP) on a continuing basis?
9. Are you in a medical specialty with active clinical research?
10. Do you have lots of identifiable patients who might participate in clinical trials?
11. Will your partners or hospital administration whole-heartedly support your clinical research activities?
12. Are you willing to invest the time, money and other resources necessary to get started in clinical research?
13. Are you prepared to dedicate significant staff resources to clinical research (and is your staff willing to do the extra work)?
14. Do you currently employ or are you willing and able to hire an experienced study coordinator?
15. Do you have a back-up plan in case your study coordinator leaves?
16. Are you located in a relatively low-cost area?
17. Are you familiar with hidden costs of clinical research such as looking for studies, evaluating protocols, negotiating clinical trial agreements and budgets, completing regulatory paperwork, and attending investigator, site initiation, and other meetings?
18. Do you have space in your office for study activities and storage of study documents, drugs and materials?
19. Are you detail-oriented?

20. Is your office well-organized and your staff self-sufficient?

21. Does your medical malpractice insurance cover clinical research?

Author

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information, consulting and training services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.

