

# Journal of Clinical Research Best Practices

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## **TRIALS IN THE FAST LANE:**

### **“ACCELERATING CLINICAL TRIALS: BUDGETS, PATIENT RECRUITMENT, AND PRODUCTIVITY”**

Cutting Edge Information, May, 2004, \$6,995, [www.AcceleratedClinicalTrials.com](http://www.AcceleratedClinicalTrials.com)

Review by Norman M. Goldfarb

At first glance, the eye-popping price sounds prohibitive, but this report is packed with hundreds of insights, any one of which would easily justify the cost for even the smallest pharmaceutical or biotech company engaged in clinical research. Any company in this industry interested in accelerating and reducing the cost of its clinical research programs – and who isn't? – should seriously consider investing in this report, if only to justify initiating or pressing forward with business practice improvement programs. CROs that want to understand industry best practices and provide that advice as a value-added service should also consider buying the report.

The report has been a big success for Cutting Edge Information, ranking in its top 10% by copies purchased. Its 153 pages include over 50 charts and numerous best practice benchmarks. It is primarily based on original research that Cutting Edge Information conducted in 2003-2004 with 100 organizations, including many large pharmaceutical and biotech companies. For most of the charts, about one-quarter of the firms surveyed provided data. The reader can easily interpret most of the results, and the authors are available for any needed clarifications. There is very little padding in the report; it's almost all results, interpretations and observations.

The report covers the following topics:

- Investigator recruitment and Incentives
- Patient recruitment
- Patient retention and compliance
- Clinical trials investment
- Clinical affairs budgeting process
- Performance measurement
- Process improvement
- Clinical research team structure
- Re-prioritizing the investigator meeting

The following insights and data are characteristic:

- Clinical affairs consumes an average of 37% of R&D budgets
- Despite decades of practice, sponsors underestimate the time required to complete 80% of studies, with the average Phase I study running over by 42%, Phase II study running over by 42%, and Phase III study running over by 30%. The average Phase III completes over six months behind schedule.
- Only 33% of sponsors track subject retention rates, despite an industry rule-of-thumb that only 75% of randomized subjects produce evaluable data.
- 60% of study duration is consumed by site enrollment, subject enrollment, and subject retention. The other 40% is about equally divided into pre- and post-study activities.
- The three most important factors in recruiting investigators are (a) budget, (b) a pre-existing investigator relationship, and (c) novelty of the study drug.
- The average Phase III study enrolls 1,417 subjects at 83 sites (17 subjects per site).
- The presence of sponsor executives at an investigator meeting demonstrates the importance of the study and strengthens the relationships mentioned above; talks by too many department representatives clog the agenda.
- The best way to improve subject recruiting is to train site personnel.
- Work through sales representatives to obtain patient referrals from other physicians.
- The most-effective websites for subject recruitment are operated by patient advocacy groups.

- Increase subject retention by giving subjects a puzzle to complete and return at the next visit for a small prize.
- One sponsor believes that its undefined process for requesting supplemental funds discourages such requests by study managers.
- Sponsors generally allocate 10-14 weeks for the period from final-protocol to first-subject-in, and 5-7 weeks from last-subject-out to data lock.
- Some sponsors have developed standard CRFs for use (with modifications) in all studies.
- Study drug delivery snafus are minimized by appointing a single person to be responsible.

A close reading of the report will reveal a few ambiguities in the results. For example, it's not clear whether sponsors measure site retention during a study or across studies. These ambiguities can be resolved by requesting a copy of the survey instrument.

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