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## "Patient and Investigator Recruitment"

**Industry Standard Research, 2009, 362 pages, $4,900**

**Review by Norman M. Goldfarb**

"Patient and Investigator Recruitment" presents remarkable insights into investigator and study subject recruitment. The report's survey methodology is impressive. First, the authors surveyed sponsors, CROs, sites and subjects to obtain a "360°" perspective. Second, they asked creative questions to find out what is really going on. Third, some of the questions requested free-text responses, which the authors scored and also included verbatim in the report for additional insights.

- Eighty percent of respondents who have not participated in a clinical study would be interested in participating. Sixty-nine percent of respondents who have not participated in a clinical study attribute it to not having been made aware of any studies. There is clearly room for more outreach. On the other hand, 39% of research participants are unlikely (<30% likelihood) to recommend study participation to a friend. We clearly have a word-of-mouth problem.
- The mean average subject recruiting budget is $3,750/subject in Phase II and III studies.
- Twenty-five percent of sponsors and CROs do not conduct market research with potential subjects. Forty-three percent conduct such market research for 20% or fewer studies. Market research seems well-advised before spending millions of dollars on recruitment.
- Research participant interest in studies drops off rapidly when driving time to the site exceeds 20 minutes. The nature of the study, the therapeutic area, and the geographic location affect this result. Fifty percent of respondents would prefer study visits in their homes, 16% would not, and 34% were indifferent.
- Only 8% of sponsor personal stated that sites selected by CROs perform better than sites selected by sponsors. Forty-eight percent say the opposite. Given that most CROs tout their investigator databases, this is a remarkable finding.
- According to 56% of sponsor personnel, IRBs have caused an increase in the time needed to conduct a clinical study over the past 12 months. According to 8%, they have caused a decrease. It may be that IRBs are reviewing studies more carefully, but this trend needs to be reversed.

A few of the free-text responses to a question about site selection are as follows:

- Finding investigators that believe in the product, have the time and resources to dedicate to the study, are responsive to the sponsor, are responsive to study issues, and are willing to provide input and give advice to pros/cons of a study. We obtain this through calls with PIs prior to the start of the study asking very specific questions. This does become subjective for a PI with whom we have no prior experience.
- Good feasibility and solid prestudy visits. Oftentimes, visits are not thorough in the review/discussion of the protocol and study requirements, and by the time we reach the site initiation visit, the physician disagrees with eligibility criteria, overall study design, etc.

- It has to do with the investigator understanding that THEY are not really the drivers; their STAFF is. Someone who understands that will be a good investigator because they will hire good people to run their trials.
- Identifying those investigators who are still interested in research and care for their patients. Cannot have investigators who basically do it for money and delegate just about everything to their nurse and are not available to speak with the CRAs or the sponsors. The investigator must have some interest in the science of the product and be willing to put in the effort to recruit patients. I believe most non-productive (enrollment) sites have the patient pool but may be not as proactive in searching for the right patient. The same goes for quality of work during the study. Need to have dedicated and committed staff in order to succeed. Experience is also needed, but not, in my opinion, as much as someone who is committed to what they signed up for.

The report includes 352 charts and tables. A number of tables compare individual CROs, although the sample sizes are too small to be definitive. The report is available at http://www.isrreports.com.

**Reviewer**

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.