

"Phase IV Clinical Trials: Best Practices in Post-Marketing Study Management"

Cutting Edge Information, 2011, 197 pages, \$7,695

Review by Norman M. Goldfarb

"Phase IV Clinical Trials: Best Practices in Post-Marketing Study Management" includes analysis of over 170 charts and figures in three sections:

- Study Management, Oversight and Strategy
- Phase 4 Trial Timelines, Activities and Performance Metrics
- Phase 4 Trial Budgets, Staffing and Outsourcing

The report includes numerous interesting findings, including the following (for the 20 U.S. and E.U. pharmaceutical companies surveyed):

- There are four main types of Phase IV studies: investigator-initiated (IIT) (31%), comparator (29%), registries and observational (21%), and large simple safety (15%).
- Sponsors conduct 82% of Phase IV studies on their own initiative, with the balance being required or requested by the FDA or other regulatory body. The most common reasons to conduct post-marketing studies are to identify or demonstrate efficacy of new dosing regimens and formulations, prove the actual benefit of a drug that was approved based on surrogate endpoints, identify or test for new indications, and engage customers, i.e., physicians (presumably in scientifically valid studies).
- When the FDA requires a study that the sponsor considers impractical to enroll, the best strategy is to make a good faith effort and then share the initial disappointing results with the FDA as justification to redesign the study.
- The number of subjects per IIT study has a bimodal distribution, with most sample sizes around 10 or 50-100. Similarly, cost per subject is either about \$1,000-\$2,000 or \$8,000-\$12,000.
- Study sponsors outsource 68% of large simple safety studies and 30-40% of the others.

The report is available at <http://www.cuttingedgeinfo.com>.

Reviewer

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