

"Investigator Initiated Trials: Building Superior IIT Capabilities"

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Review by Norman M. Goldfarb

"Investigator Initiated Trials: Building Superior IIT Capabilities" follows up on the authors' 2006 report, "Managing Investigator Initiated Clinical Trials: Structure, Process and Strategy" with new findings on IIT management best practices.¹

Investigator-initiated trials are clinical studies that are conceived and executed by the investigator. The investigator holds the IND and takes on the responsibilities of the sponsor. A pharmaceutical, biotech or medical device company may supply the test article and cover some or all of the costs, but it does not monitor the research site or manage the data.

The authors surveyed IIT executives from 18 pharmaceutical and biotech companies. Data is presented in 147 charts and figures. The report is divided into four sections:

- The strategic role of IITs
- Overview of the IIT selection process
- Building an IIT infrastructure
- Program profiles

Companies support IITs to accomplish a variety of objectives:

- Product-related goals such as expanding off-label use
- Publication goals such as establishing credibility for new products
- Clinical development goals such as, in essence, conducting feasibility studies
- Relationship goals such as building relationships with key opinion leaders

Historically, medical product companies have handled IITs informally, with mixed results. Unwelcome outcomes have included:

- The "owner" of the product was not aware of the IIT research.
- IIT studies generated articles that conflicted with the company's articles.
- IIT studies competed for subjects with studies sponsored by the company.
- The company's safety department did not adequately track adverse events.

Since the last report, the percentage of survey respondents with central IIT management groups has grown from 50% to 75%. One factor driving adoption is the phenomenon of "idea shopping," in which investigators hunt around a large company for a funding source that may have little concept of the strategic implications of a study. For example, the company may not want to fund research that interferes with the market positioning of a different drug.

Most centralized groups handle logistical functions such as collecting proposals, supplying test articles, and tracking progress. Some of them play a more strategic role in establishing policies and priorities. Nevertheless, respondents with such groups reported inadequate knowledge of names of the investigators, amount of funding, trial status, planned uses for the findings, and even the number of IITs underway.

On average, 45% of IIT proposals are funded, at an average cost of \$137,000 per proposal, including the cost of the test article when provided. Sixty percent of funded IITs generate

publications, with a range of 30% to 100% by respondent. The report did not ask survey respondents to classify publication findings as favorable or unfavorable.

IIT management groups find that some investigators want a lot of hand-holding, while others prefer a hands-off approach. These preferences may not align with the sponsors' perceptions of the support each investigator needs to conduct successful trials.

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

Reference

1. Review: "Managing Investigator Initiated Clinical Trials: Structure, Process and Strategy", Norman M. Goldfarb, Journal of Clinical Research Best Practices, January 2007

Reviewer

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