

## **"Managing Investigator Initiated Clinical Trials: Structure, Process and Strategy"**

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**Review by Norman M. Goldfarb**

"Managing Investigator Initiated Clinical Trials: Structure, Process and Strategy" offers comprehensive insights and "how-to" advice for companies that want higher rewards and lower risks from their investigator-initiated clinical trial (IIT) research.

The authors surveyed IIT executives from 18 pharmaceutical, biotech and medical device companies. Data is presented in 42 charts and figures. The report is divided into seven sections:

- IIT Management Structure and Budgets
- Building an IIT Department from Inception to Strategic Integration
- Streamlining the IIT Proposal Receipt Process
- Directing the IIT Proposal Evaluation Process
- Enhancing IIT Management and Tracking
- Strategic Integration of IIT Results
- IIT Performance Measurement and Value Assessment

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.

IITs harness investigator experience and creativity to explore new, off-label therapeutic areas, populations and treatment regimes. The data may be sufficient for an FDA application. If not, companies can follow-up with more extensive research. IITs can also strengthen relationships with thought 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.

Survey respondents reported over 40% growth in IIT research from 2005 to 2006. The future trend is unclear. On one hand, IIT research is relatively creative and economical; on the other, it is relatively uncontrolled. One possible scenario is that the growth rate may decline or even reverse, but study quality will increase.

About six years ago, some companies began to create centralized functions and formal processes to manage IIT research. 50% of survey respondents have dedicated teams to manage IIT research. About 30% have formal processes.

Some of the other interesting findings in the report include:

- Three-quarters of IIT studies are for Phase IV studies.
- Survey respondents fund almost half of the proposals they receive.

- Smaller companies, on average, allocate a higher percentage of their research budgets to IITs than do larger companies.
- Two-thirds of companies respond to proposals within two months.
- In theory, companies favor studies that support their strategic objectives, but almost half of the respondents cited the need for more strategic input.

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

### **Reviewer**

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