

## **"Investigator Initiated Trial Management"**

**Cutting Edge Information, 2011, 111 pages, \$7,695**

**Review by Norman M. Goldfarb**

"Investigator Initiated Trial Management" includes analysis of more than 50 charts and figures in four sections:

- Investigator Initiated Trial Management Structures and Functional Involvement
- IIT Submission Review and Systems
- IIT Spending and Budgets
- Setting Corporate IIT Strategy

The report includes numerous interesting and practical findings, including the following (for the 15 pharmaceutical companies surveyed):

- IITs comprise 42% of clinical studies for the typical firm.
- Eighty percent of the firms have dedicated IIT functions.
- Eight-three percent of IITs generate publications for the typical firm.

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.

Companies support IITs to accomplish a variety of objectives:

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

Centralized IIT management functions have avoided numerous problems, including the following:

- The "owner" of the product was unaware of the IIT research.
- IIT studies generated articles that duplicated or conflicted with the company's articles.
- IIT studies competed for subjects with studies sponsored by the company.
- The company's safety department could not adequately track adverse events.
- The company's compliance department could not track payments to investigators.

Since 2006, the percentage of survey respondents with central IIT management groups has grown from 50% to 80%. One among many factors driving adoption is the phenomenon of "idea shopping," in which investigators (or their medical liaisons) 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.

Many IIT management functions consist of only one or two people, which might be adequate to process incoming proposals but inadequate for the additional responsibilities of study oversight and regulatory compliance.

The U.S. Office of Inspector General (OIG) actively investigates possible anti-kickback violations, so firms should conduct fair market value (FMV) reviews of IIT proposals and monitor aggregate payments to specific investigators. The Sunshine Act will increase attention on payments to investigators.

Firms should employ short, simple applications to lower the hurdle for potential investigators; more detailed plans can be collected later. Online applications increase efficiency but do not replace the role of medical science liaisons in encouraging and guiding potential investigators.

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

### **Reviewer**

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