

"Clinical Outsourcing Strategy: Selecting Partners and Managing Relationships"

Cutting Edge Information, 2009, 90 pages, \$7,695.00

Review by Norman M. Goldfarb

"Clinical Outsourcing Strategy: Selecting Partners and Managing Relationships" is Cutting Edge Information's first report focused on clinical research outsourcing. Given the substantial role that contract research organizations (CROs) play in clinical research, it's about time.

The report has three sections:

- Clinical Outsourcing Strategy
- CRO Selection and Contract Negotiation
- Managing CRO Relationships

Thirty-four charts and figures, accompanied by interpretative discussion, provide important perspectives on clinical research outsourcing, for example:

- Data management (68%), Phase I tasks (63%), and site management (58%) are outsourced by the most study sponsors, while medical writing (26%), trial supplies (37%), and biostatistics (47%) are outsourced by the fewest.
- Fifty-eight percent of study sponsors outsource to full-service trial management CROs.
- The highest priority in outsourcing is meeting deadlines. Work quality and relationship management have intermediate importance. Quoted cost is significantly less important because of confounding factors such as the difficulty in forecasting costs in clinical trials and the negative economic implications of poor communications.
- Smaller study sponsors find little benefit from preferred-provider relationships with CROs that do more business with other study sponsors.
- In the average Phase IIIa trial, study sponsors issue 3.9 requests-for-proposal (RFPs), receive 3.5 proposals back, and issue 2.0 contracts.
- In the average Phase IIIa trial, it takes 12.5 weeks from RFP to project kick-off, with proposals taking 2.4 weeks, selection 3.7 weeks, and project kick-off 6.4 weeks.

Cutting Edge Information's analysts consulted with 18 pharmaceutical, biotechnology, medical device, and service provider firms in the development of this report.

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

Reviewer

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