

"Late Phase Market Dynamics"

Industry Standard Research, 2010, 153 pages, \$6,800

Review by Norman M. Goldfarb

"Late Phase Market Dynamics" presents numerous insights into the outsourcing market for late-phase research. The authors surveyed 149 industry professionals, mostly from pharmaceutical and biotech companies in North America and Western Europe, as well as a few from medical device companies and companies based in other parts of the world.

The report includes the following types of studies in "late phase": Phase IIIb, Phase IV, health economic outcomes, risk management programs, head-to-head comparative effectiveness, clinical experience, disease registries, product registries, pregnancy registries, post-marketing safety surveillance, patient-reported outcomes, pharmacoepidemiologic, large simple safety and compliance/adherence, and medical/product utilization and expanded access programs.

A few of the insights are as follows:

- Phase IIB, Phase IV, and health economic studies are the fastest segments of the late-stage market.
- Outsourcing decisions are most commonly centralized in clinical operations, but decentralized decision-making is also common, as is decision-making by medical affairs.
- Quintiles, Covance, PAREXEL, PPD and Icon are the leading late-stage contract research organizations (CROs). UBC is the most likely to exceed performance expectations.
- The region of Central and Eastern Europe is, by far, the most important for subject recruitment. China is, by far, the most important as part of a commercial expansion strategy.
- The most important criteria for client satisfaction are timeline management, site/subject recruitment, and budget management. Regression analysis revealed proactive issue management as another important criterion. Service providers most often lose bids because of high price, lack of therapeutic expertise, and lack of clinical development knowledge.

The report includes 173 charts and tables. It is available at <http://www.isrreports.com>.

Reviewer

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information, consulting and training services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.