

"State of the Clinical Trials Industry 2009: A Sourcebook of Charts and Statistics"

CenterWatch, 2009, 548 pages, \$699

Review by Norman M. Goldfarb

"State of the Clinical Trials Industry 2009: A Sourcebook of Charts and Statistics" is a comprehensive collection of data and analysis on clinical research. The book includes over 600 charts, tables and figures, more than 400 of them new or updated. Much of the data is original, based on CenterWatch's benchmarking surveys of research sites, sponsors and CROs.

The book has 12 chapters:

- 2008 in Review
- Industry Sales
- R&D Expenditure
- Clinical Development
- Therapeutic Areas and Pipelines
- Sponsors
- Contract Research Organizations
- Outsourcing
- Investigative Site Infrastructure and Operations
- Study Volunteers
- U.S. Regulatory
- Worldwide View

This book has been selected for
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Essential reading for clinical research professionals

A few of the important findings in the book include:

- According to a survey of PhRMA members, spending on Phase IV trials grew 39% from 1996-2000 (\$0.9 to 1.3 million per year), leaped 175% in 2001, and then grew 70% from 2001 to 2006 (\$3.9 to \$5.6 million).
- In 2007, U.S. sites saw "contract & budget negotiation & approval" as the number one cause of study initiation delays, "patient recruitment & enrollment" as number two, and "protocol amendment & refinement" as number three. In Europe and Canada, in 2008, the top three causes, in order, were "availability of study drug," "investigator selection," and "protocol design & refinement."
- Enrollment delays 70% of trials for more than one month in the U.S., 56% in Europe and Canada, 45% in Asia-Pacific, and 41% in Latin America.
- From 1994 to 2009, the market share of independent, community-based research sites increased from 37% to 76%.
- In 2007, U.S. research sites rated 71% of sponsors and 64% of CROs good to excellent.
- The number of active IRBs in the U.S. declined from 1,473 in 2000 to 1,072 in 2007.

The book includes news stories and analytical pieces, such as:

- **The Ethics of Subject Payment.** Many different types of studies provide payments, ranging from \$10 to complete a survey to more than \$3,000 for healthy subjects to

participate in a phase I trial. Newspapers, magazines and websites routinely run advertisements declaring that subjects will be paid for their participation, often specifying the amount of money. Some people manage to earn a living as so-called "professional guinea pigs" and travel around the country in search of lucrative clinical trials. Last month, The New Yorker interviewed a few of them but never estimated how many professional study participants there are in the U.S. or how many Americans volunteer for phase I studies overall each year. It failed to describe how widespread the problem is or if it is limited....

- **Site Training on EDC Improves.** The success of using electronic data capture (EDC) in a clinical trial can depend, in many cases, on how well the clinical research coordinators and other investigative site staff are trained in the use of the EDC system. According to a recent CenterWatch training survey, which reflects the experiences and viewpoints of study coordinators and other investigative site staff, more than half of the respondents indicated that the effectiveness of EDC training has improved during their career. But at the same time, site staff personnel report that they continue to face enormous challenges with both EDC technology and training, which in some cases has forced sites back to paper case report forms (CRFs)....
- **FDA Debarment Failures a Wake-Up Call for CROs, Drug Sponsors.** Leading contract research organizations (CROs) have begun to review their investigator selection and screening processes in the wake of a Congressional report charging that the U.S. Food and Drug Administration (FDA) has failed to carry out its duties in debarment researchers and drug makers that commit fraud. The report, made public in February by minority committee staff of the House Committee on Energy and Commerce, details many problems with the FDA's debarment process and raises questions about the agency's willingness to pursue corruption. According to U.S. Rep. Joe Barton, R-Texas, who released the report, the FDA's failure to consistently ban companies and individuals convicted of crimes from participating in clinical trials undermines "the integrity of FDA's approval process."...
- **Central and Eastern Europe Triples Global Trial Participation.** The Central and Eastern European (CEE) region claims an ever-increasing share of the number of global clinical trials initiated. Five years ago, the CEE region filed only 3.8% of all Form FDA-1572s, but last year the region represented double that percentage of filings at 7.9%. The FDA Form-1572 must be filed by the investigator before conducting the clinical trial. Western Europe's 1572 filings were less than double those of CEE last year at 11.6%, up less than one percent from five years ago when it had triple the market share in filings globally as CEE.

The book is available at <http://www.centerwatch.com/>.

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