

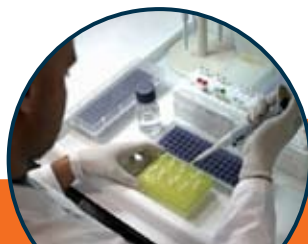
Clinical Research Organizations & the Drug Development Process

It would be easy to believe that clinical drug trials are only conducted by pharmaceutical companies, universities or government researchers. In fact, the majority of Phase I-IV clinical trials are conducted by companies known as contract Clinical Research Organizations (or CROs), on behalf of pharmaceutical companies.

CROs are recognized as experts in the clinical research process. They provide testing facilities around the world, knowledgeable staff, trial management expertise, therapeutic knowledge, and technology, all designed to make the drug development process safe for trial participants and efficient for sponsors. The largest global pharmaceutical companies and highly specialized niche organizations all can take advantage of CROs' drug-development services, including studies of new molecules, all phases of clinical testing, and pre-approval and post-marketing research.

Why do sponsors outsource the management of trials to CROs? One major consideration is cost. According to the prestigious Tufts Center for the Study of Drug Development (CSDD), clinical trials represent more than 60 percent of the cost of developing a new medication, which averages more than \$800 million invested over 10 to 15 years for each drug that successfully navigates the path from laboratory to pharmacist's shelf. The pharmaceutical industry estimates that only 250 of every 5,000 to 10,000 compounds screened in its labs enters preclinical testing. Of those, five enter human clinical trials, and just one is approved by regulators such as the U.S. Food and Drug Administration (FDA).

In 2004, the pharmaceutical industry spent nearly \$39 billion on drug research and development. With costs growing 15 percent annually since 2001, sponsors have increasingly turned to CROs to streamline the clinical trial process. In 2004, leading CROs managed 23,000 Phase I-IV clinical trials worldwide, monitored more than 150,000 clinical investigators and enrolled more than 640,000 new subjects, according to the Tufts CSDD.



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The Value of Outsourcing

Outsourcing enables sponsors to better budget their trial expenses and frees them from having to hire additional staff during peak cycles of development, then cut back when the development pipeline slows. In turn, this shift in resources allows biopharmaceutical companies to invest more in the basic R&D functions necessary to identify promising new compounds, to manufacture products that meet regulatory requirements, and to market their products to customers.

In addition, the Tufts CSDD found that trials with extensive CRO involvement are more likely to stay on schedule. Typically, studies managed by CROs send their data to regulators more than 30 days closer to their projected submission dates, and even larger, more complex trials are completed more quickly when they have a high degree of CRO involvement.

CROs ensure that trials are run according to the developer's protocol by managing the recruitment and selection of trial participants, collecting accurate trial data, and continuously monitoring the doctors and patients participating in each trial.

The Association of Clinical Research Organizations (ACRO) represents companies whose business focus is clinical research. The Association helps members improve the quality, efficiency and safety of biomedical research, and represents the industry to customers, regulators, legislators and the public. ACRO seeks to foster an environment in which laws, regulations and public policy benefits its members, their customers, and, most importantly, the patients who may live longer and better lives because of the development of new treatments.

To learn more about how ACRO and its members help the pharmaceutical, biotechnology and medical device industries with their clinical trial requirements, please contact us.

