

Clinical Research Organizations & the Drug Development Process

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 policies benefit its members companies, their customers, and, most importantly, the patients who may live longer and better lives because of the development of new treatments.

Clinical Research Organizations (CROs) offer independent product development services for the pharmaceutical, biotechnology and medical device industries. Specifically, they provide testing facilities around the world, knowledgeable staff, trial management expertise, therapeutic knowledge, and technologies designed to make the drug development process as efficient and safe as possible, for both trial sponsors and participants. Through CROs, sponsors – from the largest pharmaceutical companies to smaller, highly-specialized niche organizations – can take advantage of services that include studies of new molecules, all phases of clinical testing and pre-approval and post-marketing research.

Efficiency and Quality

While CROs are recognized as experts in the clinical research process, ACRO's members strive to enhance their value to sponsors by actively addressing the research and development needs of the biopharmaceutical and medical device industries. According to a survey by the prestigious Tufts Center for the Study of Drug Development (CSDD) – the first independent, third-party examination of the CRO industry's rapid growth – the increasing participation of CROs in the drug-development process has increased the speed and efficiency of the pharmaceutical industry's product pipeline.

CROs ensure that trials are run as designed in the developer's protocol by managing the recruitment and selection of trial participants, collecting accurate data and continuously monitoring both investigators and patients participating in the trial.

In addition, the Tufts CSDD survey found that trials making high use of CROs stay closer to schedule than those with less CRO involvement, sending their data to regulators more than 30 days closer to the projected submission date. Even larger, more complex trials were completed more quickly when they had a high degree of CRO involvement.



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The Sponsor's Advantage

With the cost of drug development rising annually, sponsors increasingly turn to CROs to run their clinical trials. 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.

Trial sponsors know that expanding and contracting clinical research staff to meet the needs of the product development pipeline can be costly. Engaging CROs allows sponsors to streamline their product development process and concentrate on their core competencies: basic research that leads to the discovery of new compounds or devices, manufacturing products that meet international regulations, and marketing approved medicines, biologics and medical devices.

Clinical trials represent nearly 40 percent of the cost of developing new medications. On average, it requires an investment of close to \$1 billion, spent over 10 to 15 years, to bring a drug from the laboratory to the pharmacist's shelf. The pharmaceutical industry estimates that just 250 out of 5,000 to 10,000 compounds screened in the lab ever enter preclinical testing. Of those, five enter human clinical trials, and one is approved by the regulators, such as the Food and Drug Administration (FDA) in the United States. In 2004, pharmaceutical companies spent nearly \$39 billion on drug R&D.

To learn more about how CROs help pharmaceutical, biotechnology and medical device companies with their clinical trial requirements, please contact us.

