



## The Role of CROs in Clinical Trials

From inception to launch, a drug's development spans some 15 years and requires nearly \$1 billion. With that level of time and money invested, pharmaceutical companies feel real pressure to get their products to market so they can begin recouping their investment. However, before they can distribute their product, it must complete a course of clinical trials, a series of phased tests that ensure its effectiveness and safety on steadily larger groups of patients.

### Partners in Research

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 trials are conducted by Clinical Research Organizations, or CROs, on behalf of pharmaceutical companies. These businesses provide specialized services in the design and conduct of clinical trials, the gathering of accurate data, and the submission of results to appropriate regulatory agencies. CROs provide testing facilities, trial management expertise, therapeutic knowledge and technology, all designed to make the drug development process safe for trial participants and efficient for sponsors.

Both global pharmaceutical firms and highly specialized niche organizations take advantage of CROs' drug-development services. In large part, the type of assistance a product's sponsor needs depends on the sponsor itself. For example, a small biotechnology company may seek more help complying with regulatory requirements than a large, brand-name pharmaceutical company. In the future, pharmaceutical companies will most likely place greater emphasis on risk management, adverse-event reporting and patient safety, all areas in which CROs have vast expertise and strong performance records. Regardless of scope, CROs have the ability to tailor their resources to address each individual client's requirements.



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### Core Roles

Because clinical trials represent a significant portion of a new medication's development cost, the budgetary advantages of engaging CROs can be significant. Outsourcing enables sponsors to better plan for 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 allows pharmaceutical firms 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 focus of CROs on clinical research activities allows them to address each trial's requirements more efficiently. As a result, trials with extensive CRO involvement are more likely to stay on schedule, according to the Tufts Center for the Study of Drug Development (CSDD). Typically, studies managed by CROs send their data to regulators more than 30 days closer to their projected submission dates, the Tufts CSDD found, and even larger, more complex trials are completed more quickly when they have a high degree of CRO involvement.

The Association of Clinical Research Organizations (ACRO) represents companies whose business focus is on conducting 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 will 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.

