



## The CROs Contribution to Drug Development

Over the last five years, a significant proportion of clinical trial resources has shifted from pharmaceutical companies to contract Clinical Research Organizations, or CROs. A 2006 survey by the Tufts Center for the Study of Drug Development (CSDD) found this realignment has increased the speed and efficiency of the pharmaceutical industry's product-development pipeline while maintaining clinical-trial data quality and high levels of regulatory compliance.

Simply put, pharmaceutical, biotechnology and medical-device companies are taking increasing advantage of the CRO industry's focus and using it to complement their own broader range of activities.

### Expertise at work

As their name implies, CROs are expert in a vital area of drug development: the design and conduct of clinical trials and the reporting of their results. Outsourcing to CROs 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 shift in resources allows pharmaceutical 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 these products to customers.

Because CROs specialize in clinical research, they focus on maintaining the staff, facilities, technology and therapeutic expertise necessary to run clinical trials that are safe for participants and efficient and accurate for sponsors. They ensure trials are conducted according to the developer's protocol, manage the recruitment and selection of participants, collect accurate trial data, and continuously monitor the doctors and patients involved in each project. This range of activities is complex, requiring experience with good clinical practices, knowledge of day-to-day operations, outreach to targeted communities from whom participants can be drawn, and knowledge of regulations around the world.



227 Massachusetts Avenue, NE  
Suite 300  
Washington, DC 20002  
T 202 543 4018  
F 202 543 5327  
E [info@acrohealth.org](mailto:info@acrohealth.org)  
[www.acrohealth.org](http://www.acrohealth.org)

contact details

## Survey highlights

Specifically, the Tufts survey found:

- Since 2001, spending by pharmaceutical and biotechnology companies on contract clinical research services has grown 15 percent annually, outpacing the 9 percent annual increase on overall development spending.
- Between 2001 and 2004, headcount among major CROs grew 6 percent annually while project-sponsor headcount remained flat, indicating an increased reliance on CROs by the pharmaceutical industry.
- Drug companies reported that projects with a high reliance on CROs stayed closer to schedule than those making less use of CROs. Typically, projects that relied heavily on CRO participation submitted their data to regulators more than 30 days closer to the projected submission date than projects with less CRO participation.
- Even larger, more complex trials are completed more quickly when they have a high degree of CRO involvement.

The Tufts study represents input gathered through a series of wide-ranging interviews with representatives of 31 pharmaceutical and biotechnology companies of varying size. The researchers gathered data on 79 New Drug Applications (NDA) and four Biologics License Application (BLA) submissions made between 2000 and 2004. In addition, the researchers collected data from member companies of the Association of Clinical Research Organizations (ACRO).

The study was commissioned by ACRO to examine the contribution CROs make to the pharmaceutical industry's overall development capacity, and to assess the impact clinical outsourcing has on the performance of development projects. It represents the first independent, third-party examination of CRO industry growth.

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.

