

## Serving A Global Enterprise

Clinical trials are the bridge connecting theory and practice, the laboratory and the treatment of disease, illness and injury. They are complex and vital processes that determine whether a drug or medical device is safe for use by the general population. Beginning with a handful of volunteers, they ensure that treatments which seemed promising in the laboratory are, in fact, effective and safe in practice.

Each year, approximately 80,000 clinical trials focus on the development of new drugs, new medical devices and new treatments. They involve more than 30,000 doctors and millions of patients worldwide. They're part of an extremely time-consuming and expensive process. The Tufts Center for the Study of Drug Development estimates that it costs nearly \$1 billion and requires between 10 and 15 years to develop a new prescription drug and get it approved for market use. Nearly 40 percent of that cost is invested in the four phases of clinical trials.

Drug development is a mammoth undertaking, involving tens of thousands of professionals. Their work has resulted in cures for conditions that within the last half-century were considered untreatable. The risk of dying from cancer, for example, continues to decline in the United States according to the National Cancer Institute, as does the mortality rate from heart disease and stroke. (Today, some 146 medicines for heart disease and stroke alone are either in clinical trials or awaiting regulatory approval.) As impressive as such momentum is, it doesn't represent the full scope of the industry's drug-development efforts. Of every 5,000 to 10,000 medicines examined in the laboratory, only five enter clinical trials. Of those five, just one will be approved by regulators.

### Speaking with a single voice

Today, dozens of pharmaceutical firms are at work, some of them global corporations, others niche organizations focused on a specialized treatment approach or single condition. Any effort so dynamic and broad in scope is bound to be complex.



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Recognizing this, Clinical Research Organizations (CROs), the pharmaceutical industry and regulators, work together to create strategies that will increase the efficiency of drug development without compromising patient safety at any stage in a medication's lifecycle, whether it's in research, testing or after its introduction to the market. The Association of Clinical Research Organizations (ACRO), which represents the world's leading CROs, has been a close partner of the U.S. Food and Drug Administration (FDA) on its Critical Path Initiative, an ambitious effort to streamline the drug development process, and of the European Union officials implementing their Clinical Trials Directive (2001/20/EC). Like its colleague organizations in the pharmaceutical and biotechnology industries, ACRO works with officials in both established and emerging markets to facilitate the development of new drugs and new treatments for the patients who need them, while ensuring the highest ethical and scientific standards.

The Association of Clinical Research Organizations, or 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.