



## CROs as Partners in Safety

Scientifically sound, properly executed clinical trials must be conducted for a new drug or medical device to move from laboratory to market. When regulators review a product's application, they want to see solid data – scientific results that are backed by hard numbers and proper procedures. Anything less simply delays a trial's progress.

Pharmaceutical companies, regulators, researchers and others involved in medical product development have an intrinsic commitment to the safety and well-being of patients in all phases of a product's lifecycle. These include research, manufacturing and, ultimately, commercial distribution. For Clinical Research Organizations or CROs, this commitment has resulted in a variety of best practices developed around the need to conduct trials on a foundation of patient safety. It begins with the Code of Ethics of the Association of Clinical Research Organizations, which emphasize the rights and safety of trial participants and the CRO industry's support for laws and regulations that enhance them.

Clinical trials ensure a drug's effectiveness and safety through phased testing that measures its impact on steadily larger groups of patients. It's an effort based on science – a straightforward gathering of data and evaluation of their meaning. Such efforts must be designed with patient safety uppermost in mind and conducted under a scientific methodology that's rigorously enforced. History bears out these arguments: when regulators receive data from a solid scientific effort, their review tends to be prompt and the entire drug-development process more streamlined.

### Key Steps

The entire clinical-trial process is designed around the protection of patients and the gathering of accurate data. Even before a trial begins, for example, its plan is reviewed by Institutional Review Boards, or IRBs, to ensure it will be conducted ethically and follow appropriate guidelines for the selection of participants. These boards – which are independent of both CROs and trial sponsors – do not judge a proposed product's usefulness or a study's statistical analysis plan. Their job is solely to evaluate a study's ethics in regards to participants and their safety.



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For patients, a clinical study offers the potential to make a real future difference either to themselves or to other sufferers of a particular condition. These patients cannot make an informed decision about participating in a study, however, until all of the study's aspects and implications have been simply and comprehensively communicated and fully understood. This means all written material and direct conversations among researchers, medical staff and patients must rely on plain language. Medical jargon or legalese should be strongly avoided at all times. Recruiting participants based on anything less than full disclosure could very well call the entire clinical study into question.

CROs work in a highly regulated environment. Their operations and facilities are subject to audit and they can face sanctions for instances of non-compliance. Core CRO activities – including training in good clinical practice and operating procedures, in-person monitoring of research facilities, assuring informed consent from trial participants and reporting adverse events – are all governed by the U.S. Food and Drug Administration (FDA) and other regulators and government bodies, both in the U.S. and globally.

For CROs, a properly run clinical study, with patient safety and scientific methodology rigorously ensured, is their mission – their primary focus and top priority. By running ethical studies and producing valid results, CROs are a cornerstone of the efficient product development process that pharmaceutical companies seek.

The Association of Clinical Research Organizations, or ACRO, represents companies whose business focus is 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.

