Clinical Trials and Contract Research Organizations in India

Shoibal Mukherjee, MD, DM

KEYWORDS

• Clinical trials • Research • India • CRO • Research quality • Compliance

KEY POINTS

- Economics and demography are driving drug development to the developing world. India needs this opportunity to build research skills required to combat its enormous disease burden.
- A variety of global and local contract research organizations (CROs) that specialize in the execution of research to develop health care products operate in India today.
- CROs assure quality and compliance to regulations while coordinating with tertiary providers such as a site management organization and the central laboratory.
- Back room operations to manage, analyze, and report data form a bulk of the employment generated by clinical research, absorbing programmers, data managers, biostatisticians, and medical writers.
- Despite rapid growth and strong potential, India remains a minor contributor to global pharmaceutical research because of policy stagnation, regulatory gaps, and misinformed controversies in the media.

Clinical trials are integral to the development of new medicines, diagnostics, and medical devices. Because there is no other way to demonstrate the effectiveness and safety of new therapeutic modalities for human use or their equivalence or superiority over existing therapy, regulatory authorities require a series of clinical trials to be conducted and their results analyzed before a new treatment can be introduced for general consumption. Every claim that is made in the package insert of a pharmaceutical product must be backed up with evidence from clinical trials. Consequently, clinical trials account for almost 60% of the time and resources required to bring a new drug to market.[1] Yet most of this investment is wasted, because over 80% of new products tested in clinical trials fail to live up to the promise of improvement over existing therapy, and therefore have to be abandoned.

Indeed, the explosive growth of life science technologies juxtaposed with the growing complexity of the science behind discovery and development of new

Quintiles Research Private Limited, 8th Floor, DLF Square, Jacaranda Marg, DLF City Phase II, Gurgaon, Haryana 122002, India
E-mail address: shoibal.mukherjee@quintiles.com

Clin Lab Med 32 (2012) 315–320
http://dx.doi.org/10.1016/j.cll.2012.04.008 **labmed.theclinics.com**
0272-2712/12/$ – see front matter

medicines have led to a situation where, despite the plethora of new leads, the conventional research pathway in the developed world has become too expensive and increasingly unaffordable, even for the largest corporate entities.[2] The lower cost of research talent in developing countries, the larger size of study populations in countries like China and India, and the fact that the pharmaceutical markets in these countries is now approaching the size of historically large markets of Europe and North America, are driving pharmaceutical research to developing countries. In India this trend is further accentuated by public health investments being made by nonprofit organizations and investments in drug development research by the local industry. Indeed, given the fact that India is home to the world's highest disease burden in absolute terms,[3] it is imperative that the country take steps to combat that burden through prowess in the development of breakthrough health care products.

CONTRACT RESEARCH ORGANIZATIONS

The early part of the last decade saw substantial growth of clinical research capability. Many local and multinational companies set up clinical development units in the country,[4] as did several nonprofit entities and publicly funded research bodies under the Department of Biotechnology and the Indian Council of Medical Research. These units were supplemented by contract research organizations (CROs)—companies with specific specialization in the execution of research for the development of health care products. Today there are a variety of CROs operating in India—from those involved in discovery research to those specializing in the various aspects of preclinical and clinical research. The clinical CROs are the most numerous because entry barriers are relatively low.

Clinical CROs undertake execution of clinical projects on behalf of a sponsor. This practice is good for sponsors because the skills necessary to execute a clinical trial are very specific and divorced from the basic research, manufacturing, and marketing competencies that sponsors may have. For smaller sponsors who have a single or small number of products to develop, this partnership ensures that they do not have to hire an army of staff to execute a single project and then lay them off once the project is over. So, once an entrepreneur has translated an original scientific idea into a molecule that can combat disease and has put it through the animal tests required to prove that it can be given to patients without unacceptable safety risks, a CRO can be hired to conduct the clinical trials that will be required to collect the data necessary to define the use of the product by patients. CROs are generally capable of doing the rest, which includes preparing a clinical development plan, writing the clinical protocols, obtaining regulatory approvals to conduct clinical trials, contacting health care practitioners to recruit patients into the study using informed consent procedures approved by an ethics committee, ensuring meticulous documentation of the effects of the drug when administered according to the protocol, collecting and analyzing the data, and writing a final report for regulatory submission.

To accomplish these tasks a CRO usually has several departments of qualified and trained individuals: a regulatory department trained in the rules and regulations governing clinical trials; a site identification and start-up unit that maintains contact with health care professionals and institutions that may serve as investigators and sites for the study and ensures that these sites have the necessary infrastructure and staffing to undertake trials; a clinical operations group that works with the investigators at the site to train the team on the study protocol and ensure that the study is conducted in line with complex Good Clinical Practice[5] guidelines; a quality assurance department that conducts periodic audits of study to point out deficiencies if any and ensure that these are corrected and preventive measures put in place; a medical