Consistent clinical research standards benefit patients around the world

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Although the globalization of clinical trials has provided benefits to host countries, critics have focused on the rare but egregious examples of unethical practices. But large, coordinated trials by the contract research industry can encourage best practice, particularly if local countries adopt more consistent standards and oversight.

As economic prosperity comes to developing nations, diseases associated with Western lifestyles, such as cancer and diabetes, are crossing borders. Meanwhile, developing countries are quickly becoming consumers of biopharmaceutical products. With the shared burden of disease comes the need to obtain safety and efficacy profiles across worldwide populations in a way that mirrors global disease epidemiology and treatment.

Increasing access to allow for more people to participate will be instrumental in clinical trials of the future. Developed nations are home to just 15% of the world's population, yet they host three-quarters of all clinical trials. Clinical trials in emerging regions tend to take place in large urban centers where healthcare infrastructure can support research conducted according to Good Clinical Practice (GCP) and International Conference on Harmonization (ICH) standards. Compliance to these industry standards will strengthen the safety and quality of the research and increase public confidence in clinical trial participation.

Without further globalization, the pace of medical research would slow substantially. This is largely due to the reality that clinical trials are larger and more complex than they were ten years ago, and Western participation levels have peaked.

To put this in perspective, consider what would happen if late-stage oncology studies were limited to the US. According to the American Cancer Society, roughly 1.5 million people in the US were diagnosed with cancer in 2008, but only 3– 5% of US cancer patients participate in clinical trials. At this rate, with more than 1,200 late-stage global trials currently being conducted, it would take approximately six years to fully enroll volunteers if limited to the US—effectively stalling cancer research. If, however, we were to expand the available trial population worldwide, we would reduce enrollment time to less than two years, potentially delivering a new, life-saving cancer therapy to patients four years sooner.

Government institutions, academia and nonprofit organizations conduct clinical research. However, 75% of all clinical studies are sponsored by biotech and pharmaceutical companies, and a growing percentage of their work is outsourced to contract research organizations (CROs). Subject to the same oversight as their sponsors by international regulatory agencies and institutional review boards or ethics committees, CROs provide a full spectrum of drug development services to companies looking to make their fixed costs more variable, standardize clinical operations and bring medicines to market quickly.

The CRO industry has doubled in size since 2001 and is an increasingly important resource to the biopharmaceutical industry. Today, through the Association of Clinical Research Organizations (ACRO), CROs are a leading force behind the globalization of clinical research and a strong advocate for uniform regulation—both of which are crucial to the advancement of human health.

ACRO represents the largest global CROs, which have had a hand in developing nine out of every ten drugs approved in the US and Europe last year. CROs manage about 22% of worldwide drug research and development spending from preclinical to post-marketing studies, employ more than 70,000 people (half of whom work outside the US) and conduct research in more than 115 countries, from Albania to Zimbabwe. Last year, CROs conducted 9,000 clinical trials in a variety of therapeutic classes, including oncology, metabolism, cardiovascular, respiratory and infectious diseases.

These clinical trials benefit the patients, families, workers and economies of emerging countries, providing skilled jobs in areas of limited opportunity and faster access to medicines. Because first-in-human clinical trials, which generally require healthy volunteers, are almost exclusively conducted in the US, Canada and Western Europe, patients enrolled in clinical trials in developing countries typically suffer from the disease or condition under investigation. As trial participants, they get access to a standard of care that might not be available otherwise.

Results of an as-yet unpublished analysis by ACRO of international data showed no statistically significant differences in the quality of contract clinical work when comparing mature, developing and emerging regions. This is not surprising, as global CROs follow uniform standards, which require clinical workers to abide by GCP and ICH standards enforced by worldwide regulatory authorities. As such, CROs are subject to on-the-spot investigations and audits by dozens of governmental agencies.

Clearly, continued access to global markets is both beneficial and necessary to promoting worldwide human health, but ACRO members recognize that globalization goes hand in hand with the need for better, more efficient governance. Global regulatory infrastructure, which has been strengthened by in-country experience, is still developing. Since the early 2000s, ACRO and its members have been collaborating with many regulatory agencies in emerging countries to help establish standards around clinical research. In India, for example, most recently, ACRO members have been working with regulators, the Central Drug Standard Control Organization and the Drug Controller General of India to refine guidelines around the reporting of serious adverse events, compensation for trial-related injuries and timelines for clinical trial approvals. ACRO also collaborated with the Italian CRO Association and submitted comments to Italian Medicines Agency regarding a decree aimed at defining minimum education and documentation requirements for CROs doing business in Italy. The association also continues to support increased appropriations for the US Food and Drug Administration to have the necessary resources to carry out greater oversight internationally and to train and work with its fellow regulators around the world.

We all have a vested interest in ensuring that commercial, academic and nonprofit organizations engaged in clinical research follow the same consistent, ethical practices, regardless of where they operate. Consistent global standards coupled with smart regulation will not only speed the delivery of life-saving medicines to the people of the world but also improve the quality, safety and efficiency of biomedical research, encourage industry growth and investment, and, most important, increase public understanding and confidence.

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