



GLOBALIZATION OF CLINICAL TRIALS

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Today, the globalization of clinical trials is accelerating, driven by scientific and economic needs to reach more patients. The International Conference on Harmonization (ICH) advanced the trend during the 1990s by normalizing research and regulatory standards across North America, the European Union and Japan.

Globalization intensifies safety and ethical issues, as more trials are conducted in populations vulnerable to exploitation due to poverty, lack of legal and regulatory protections, and lack of adequate health care. The global research environment is especially challenging for Contract Research Organizations (CROs), which increasingly provide research services in emerging regions. CROs can help accelerate drug development in emerging countries while maintaining global standards and systems.

The benefits of this expansion include: access to new populations for clinical trials; diversifying the pool of participants; providing experience for investigators in developing countries; and broadening the global infrastructure needed for clinical trials. Drawbacks include potential ethical dilemmas, particularly where poor health care access and infrastructure may promote participation in clinical trials for the wrong reasons, and insufficient regulatory oversight in some developing countries.

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DRIVING GLOBAL RESEARCH

Medicine and medical innovation, however, must be global, for humanitarian and scientific reasons. Global studies provide greater access

to patients and offer reduced costs. There are urgent needs to study target diseases, such as HIV/AIDS in Africa, and to develop better medicines for diseases like malaria and tuberculosis that kill millions of people in developing countries. Researchers also need access to populations with specific genetic profiles in order to evaluate drug effects and optimal dosage recommendations for different ethnic groups.

The global biotechnology industry is driving development research, especially as regulations and standards are becoming harmonized on an international scale. Biotechnology research is expanding into emerging nations, including China and India, which will play major roles in the global pharmaceutical industry. China is projected to be the world's fifth largest pharmaceutical market by 2010, and number one by 2050.¹ Other Asian nations, such as Singapore and South Korea, are focusing on biotechnology to grow their economies.

Greater access to patient populations can speed clinical trials. In the traditional trial venues of North America and Europe, patient enrollment is a significant barrier to research. A 2003 survey of these sites reported that more than 70 percent of trials were delayed longer than one month and 30 percent of sites under-performed, enrolling only 5 percent of target.² Recruitment is much more timely and efficient in most developing countries and enrolling patients faster helps reduce study costs and gets medicines to those in need sooner. In some cases, however, research costs can be higher, as additional investment is needed to prepare facilities, train investigators, and administer projects complicated by distance, language, cultural, medical and regulatory practices.

COMMITMENT TO ETHICAL RESEARCH

In a global environment, the research community must ensure patient safety and ethical practices. Regulatory and scientific requirements for clinical trials provide rigorous patient protections that include: informed consent; preclinical assessment of possible harmful drug effects; safety monitoring and reporting throughout trials; protection of patient privacy; and data that is made accessible so findings can be verified.

Drug developers must work to build high-quality research capability and ensure safety and ethical standards for research in emerging regions. This is especially important for CROs, which are a primary resource to conduct trials in developing markets. As the world's leading CRO,

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» *Quintiles Transnational Corp. is powering the next generation of healthcare by providing a broad range of professional services in drug development, commercialization and strategic partnering for the pharmaceutical, biotechnology and medical device industries.*

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Quintiles requires all its global sites to provide excellent medical expertise and conduct research to ICH-GCP (Good Clinical Practice) standards. Quintiles also uses the same standard operating procedures across the globe and ensures compliance. Quintiles is a leader in providing GCP training and in developing research infrastructure in emerging nations. We have made significant contributions in India, Eastern Europe and China where we have been conducting research for more than 10 years. We are committed to improving informed consent practice and safeguards for vulnerable study populations.

In addition to full regulatory compliance with ICH/GCP, Quintiles' own internal safeguards set the highest possible standards for patient safety and ethical practice. We monitor research safety and ethics through two central organizations: CORE (Council on Research Ethics) and CODP (Council on Data Protection). We evaluate the safety and ethics of every trial we conduct, and work to enhance standards whenever possible. Ethical research, however, can only assure that potential benefits outweigh risks and that all precautions are taken to reduce risk for study subjects.

A LEADER IN A CHANGING WORLD

The CRO industry will become increasingly global in the decades ahead, emphasizing safety, quality, ethical practice and efficient, cost-effective drug development. As the leader in global clinical trials, Quintiles has conducted more than 3,300 studies at 170,000 investigative sites, involving more 2.5 million patients across 60 countries since 2000. Nearly half of patients in Quintiles projects were enrolled in developing regions. We've conducted more than 240 clinical studies in India alone, with almost 43,000 patients.

Global research is needed to address health issues. While industry-sponsored research has not solved world health problems such as HIV, malaria and tuberculosis, Quintiles is leveraging a global infrastructure to partner with government and private organizations to face these challenges. Quintiles is proud to be a pioneer in the globalization of clinical trials to make the world a better place.

REFERENCES

¹ Ernst & Young, *Unmasking China's Pharmaceutical Future*, 2005

² Clinical Trial Advisor, "Overcoming the trust gap in patient recruitment," Nov. 2006.