



THE VALUE OF

CONTRACT RESEARCH ORGANIZATIONS

THE VALUE OF CROs

Contract Research Organizations (CROs) are making an increasingly valuable contribution to healthcare by conducting the clinical trials that help determine which investigational medicines advance toward regulatory approval. In a recent report on clinical trial outsourcing, the Tufts Center for the Study of Drug Development found that CROs contribute approximately half the workforce engaged in drug research and are integral to biopharmaceutical product development.¹

» Researchers found that CROs contribute approximately half of the workforce engaged in drug development.

THE MODERN CLINICAL TRIAL

During the last 50 years, medicines tested in clinical trials have helped to add 10 years of life expectancy in the developed world.² Yet, society scarcely recognizes how this powerful invention changed life in the 20th century.

By the end of World War II, the first wave of antibiotics was reaching medical practice, and biochemistry labs were generating hundreds of new agents to treat diseases from infection to cancer. There was no formal research process to evaluate the flood of new drugs, however, and physicians had no experience and little information to prescribe them. Following the thalidomide tragedy, the 1962 Kefauver-Harris Amendment required proof that a proposed drug was safe and effective against a targeted disease.

During the 1960s, the U.S. Food and Drug Administration (FDA) implemented a rigorous drug approval process to demonstrate drug safety and efficacy. By the 1970s, the three-phased clinical development process was firmly established:

Phase I: safety and dosage studies in 20-80 healthy volunteers;

Phase II: effectiveness and safety studies in small (100-300) patient group;

Phase III: confirming studies in larger (1,000-3,000) patient population.

This research process delivered the therapeutic revolution of the last 50 years: from 1963 to 2007, the FDA approved 1,001 new drug therapies.^{3,4} These represent virtually all the pharmaceuticals in use today – from beta blockers, cancer drugs and antidepressants, to anticholesterol drugs, asthma therapies, and the first cancer vaccine.

CROs ARE INVALUABLE CONTRIBUTORS

In the effort to bring new medicines to patients faster and more efficiently, CROs are making important contributions. Tufts noted that CROs offer a significant speed advantage – notably during the start-up and close-out phases of clinical trials. The Tufts study found that by using CROs, drug sponsors were able to reduce time to final regulatory submission by more than 30 days.

CROs contribute significantly to international drug development capacity by providing world-class knowledge and skill. These industry professionals bring efficiency and experience to the drug development process. For example, the world's leading CRO, Quintiles, employs more than 50 senior medical advisors, more than 300 MDs, and almost 400 Ph.D.s. Since 2000, Quintiles has conducted more than 3,200 clinical trials in some 90 countries, involving more than 2.5 million patients. Overall, it is estimated that CROs conduct close to 25 percent of clinical drug trials, making a significant contribution to the delivery of new therapies to healthcare.

LIVING LONGER, HEALTHIER LIVES

Perhaps the greatest benefit of the clinical trial is its contribution to gains in life expectancy in the developed world over the last 50 years. From 1900 to 1950, life expectancy increased by 20 years, through the introduction of numerous vaccines to fight infectious diseases, together with improved sanitation and nutrition. Since 1950, another 10 years has been added to average life expectancy, with more vaccines and new pharmaceuticals that control chronic diseases and aging-related illnesses.²

» Perhaps the greatest benefit of the clinical trial is its contribution to the gain in life expectancy in the developed world over the last 50 years.

» *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.*

» **Quintiles Transnational Corp.**
Post Office Box 13979
Research Triangle Park, NC 27709
+1.919.998.2000
www.quintiles.com

Consider the impact of new medicines on survival rates from cancer, AIDS and heart disease. Within the last few years in the United States, cancer death rates declined for the first time since 1930, with 369 fewer deaths in 2003 and 3,000 fewer in 2004.⁵ Novel drugs helped transform treatment and survival rates in diseases, such as childhood leukemia. In the 1950s, the survival rate was 4 percent. Today, it is more than 80 percent.⁶ Before the first AIDS drug was approved in 1987, HIV/AIDS diagnosis was a virtual death sentence. HAART (Highly Active Antiretroviral Therapy), introduced in 1996, now makes HIV manageable. In 1993, the average life expectancy from diagnosis for Americans with HIV was seven years. Today, life expectancy is 24 years.⁷

According to a 2003 study by F.R. Lichtenberg, between 1988 and 2000, new drug introductions accounted for 40 percent of the increase in life expectancy.⁸ CROs have made vital contributions to developing such therapeutic advances. CROs offer benefits to the drug development process in expertise and efficiency that mean more life-saving medicines can be delivered to patients sooner.

The clinical trial continues to evolve with new sciences and technologies aimed at developing 21st century medicines that are safer and more effective. In today's complex research environment, CROs like Quintiles are helping to advance the clinical trial. Quintiles has played a role in developing or commercializing each of the world's top 30 best selling drugs and continues to pursue research innovations that bring new treatments to patients safely and efficiently.

REFERENCES

- ¹ Tufts Center for the Study of Drug Development Impact Report. (2006) Vol 8, No 1.
- ² National Vital Statistics Reports. (2002) Vol 51, No 3.
- ³ *Medical & Healthcare Marketplace Guide*, 19th Edition. Dorland Healthcare Information, 2004.
- ⁴ FDA (2007). CDER Drug and Biologic Approval Reports, at <http://www.fda.gov/cder/rdmt>.
- ⁵ Jemal, A. (2007) Cancer statistics, 2007. *CA: Cancer Journal for Clinicians*, 57: 43-66.
- ⁶ St. Jude Children's Hospital, 5-year cancer survival rates, at <http://www.stjude.org>.
- ⁷ Schackman, B.R. et al. (2006) The lifetime cost of current human immunodeficiency virus care in the United States. *Medical Care*, 44: 990-997.
- ⁸ Lichtenberg, F.R. (2003) The impact of new drug launches on longevity: evidence from longitudinal disease-level data from 52 countries, 1982-2001. National Bureau of Economic Research, June.