



# CHAMPIONING THE CLINICAL TRIAL

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Before the clinical trial, medicine was a mixture of magic, religion and healing traditions based on trial and error. For anyone born after World War II, it is hard to appreciate how limited medicine was before penicillin launched the age of antibiotics. In 1899, aspirin became the first wonder drug. During the first half of the 20th century, the typical physician's bag contained: quinine (malaria); calomel (fungicide); opium (painkiller); digitalis (heart); buchu (diuretic); ipecac (emetic); and Dover's powder (laxative).

The 1950s brought dramatic change as the first wave of antibiotics reached medical practice. Hundreds of new drugs were emerging from biochemistry labs, but there was no formal process to evaluate their safety and effectiveness and little information on prescribing them.

The first modern clinical trial, conducted by British epidemiologist Austin Bradford Hill, provided the solution. In 1946, Hill conducted a study of streptomycin to treat tuberculosis. He used a novel experimental design in which patients were assigned to treatment regimens at random in order to avoid bias. The landmark study was published in 1948 in the *British Medical Journal* and was cited as "the clearest possible proof" that tuberculosis could be halted by streptomycin.<sup>1</sup> The controlled, randomized clinical trial became the foundation of today's drug development process.

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## MODERN MEDICINE

Since the 1950s, the clinical trial has been fundamental in understanding disease processes, how medicines work in the body, and how to use medicines in clinical practice. Thanks to the clinical trial, the baby boomers became the first generation to grow up and grow old with the benefits of:

- » cancer chemotherapy;
- » beta blockers and statins for heart disease;
- » psychiatric drugs;
- » antiviral drugs; and
- » drugs for asthma, migraine, Alzheimer's, and more.

Perhaps the greatest benefit of the clinical trial is its contribution to the 10-year gain in life expectancy enjoyed by the developed world in the last 50 years. 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.<sup>2</sup> Since 2000, we've seen the beginning of a new therapeutic era with the first cancer vaccine for cervical cancer, the first gene therapy for neck cancer and the rise of biotechnology therapies.

## CHANGING TIMES

Despite these advances, society's positive view of the pharmaceutical industry has declined. Medicines that transformed healthcare in the 1950s, 1960s and 1970s were developed in a positive environment. Pharmaceutical companies were generally respected and seen as primarily interested in medical research.

Today, the pharma industry and regulators are under attack. Rare, but highly publicized, safety issues have contributed to a perceived crisis in marketed drug safety and raised questions about the ability of the research process to deliver safe medicines. Trust in pharma and drug research has been damaged.

In recent public opinion surveys:

- » 23 percent trusted clinical trial data – down from 72 percent in 1996. (*ClinTrialsAdvisor, November 2006.*)
- » 7 percent believed the pharma industry to be honest. (*Harris Interactive, October 2006.*)
- » 46 percent believed clinical trial subjects are “gambling with their health” and are “human guinea pigs.” (*Harris Interactive, June 2005.*)

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» 76 percent believed pharma to be more interested in profit than public good. (*WJS/NBC News 2005.*)

Distrust often threatens participation in clinical trials. Due to difficulties in enrolling patients, 72 percent of trials are delayed by one month. About 20 percent of study sites never enroll a single patient.<sup>3</sup>

## ADVOCATES FOR ADVANCEMENT

Restoring patient and public trust in the clinical trial is a critical step in the advancement of medical innovation. Drug developers must improve the technology and safety of the trial, while making it clear what they can and cannot do. The clinical trial measures drug efficacy and safety in a small population so that new medicines can be introduced to medical practice with an acceptable level of risk, but cannot avoid all risks for study subjects. Participants must understand the risks they are accepting in order to advance medicine, and – hopefully – to help develop a drug that can better treat their own disease. In this environment, Quintiles believes the research community must champion the clinical trial as an essential tool for medical innovation. At Quintiles, we pride ourselves on “Work Worth Doing.” We have a great responsibility in clinical research to deliver the amazing advances that are emerging from today’s discovery programs.

Quintiles’ ethical standards and review procedures ensure patient safety remains the top priority for all clinical trials. The company is also leading the way for data transparency, so drug trial sponsors have instant access to information about the conduct and status of trials. Therapies must advance to meet the challenges of modern medicine through safe, ethical clinical research. At stake is the future of medical innovation and the conquest of disease.

## REFERENCES

- <sup>1</sup> Medical Research Council Investigation. Streptomycin treatment of pulmonary tuberculosis. *British Medical Journal*, 1948; ii: 769-782.
- <sup>2</sup> 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.
- <sup>3</sup> Overcoming the trust gap in patient recruit. (2006) *Clinical Trial Advisor*, Vol 11, No 14.