Understanding Clinical Trials: Appreciating Medical Heroes

Every one of us, at some point in our lives, will face the daunting challenge of having to choose between medical options for ourselves, our family and our friends. There’s no question that clinical trials will play a large and growing role in the options to be evaluated and considered.

Progress In The Last Half-Century: Breakthroughs In The Prevention And Treatment Of Disease

Fifty years ago, many treatments we take for granted today did not exist. By investing in basic and clinical research, we have made tremendous progress. From 1980–2000, for example, the age-adjusted death rate in the USA for coronary heart disease was cut in half.

Another example of the societal benefits that clinical research has delivered is the near eradication of measles. This disease, which a “flip of a coin” what these people may not realize, such as the age-adjusted death rate for coronary heart disease was cut in half, is now one of the most preventable of all childhood diseases. Some of the main reasons for this decrease can be attributed to reductions in major risk factors like cholesterol and smoking. However, the other half of the contribution to medical breakthroughs is clinical trials.

The National Institutes of Health has invested heavily in basic science to find the theoretical basis for new treatments, however, most resources spent on clinical development of new treatments has been provided by pharmaceutical, biotechnology, and device companies. The results of these organizations, along with those of the health professionals and patients who participate in clinical trials, public health in the US would not be what it is today.

The principles on which the pharmaceutical industry has been working in recent years, however, some people believe that clinical trials are unnecessary, unethical, and profit-driven. "Department of Conduct on Humans. Such individuals would prefer their own doctor choose what therapy is best for them, rather than allow research trials to "tip of a coin." What these people may not realize is that doctors don’t always know what treatment is best because objective companies of large numbers of patients in studies is needed to sort out the truth about benefits and risks. This being the case, people should not be reluctant to volunteer for clinical trials, which are often only when it is unclear which treatment option being tested is best. A good example of this need for objective analysis and the potential benefits of research participation is the Cardiac Arrhythmia Suppression Trial, which was conducted several years ago. This study sought to prove that suppressing extrasystoles in heart beats using anti-arrhythmic drugs could save lives in patients with con- if antymicrobial drugs were stopped three or more times more likely to die than patients receiving placebo there were helping, but these drugs had un- intended consequences. As a result regardless of whether an experimental treatment is safe and effective or is harm- ful and ineffective.

Participation is a courageous act as there are numerous risks in clinical trials. But desired to bring hope to the sick and suffering. In many instances, people who are the reader with the many professionals, the public, and patients that participate in clinical trials, and develops and corrects misperceptions about clinical research. The many people who contributed to this special report deserve our thanks for helping to educate and inform a large number of people. Of course the greatest thank you and appreciation goes to all the medical heroes each year who give the gift of their participation to clinical research and the public’s health.

We are grateful to the editors of Clinical Trials, Robert W. Wachter, MD and author of the Gift of Participation in Clinical Research: From Trial Center for the Study of Drug Development, Tulane University Medical School.

Ken Getz, MD, MS 
Editorial Director

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Demystifying Clinical Trials

Human guinea pigs, unknown side effects, experimental treatments, and endless testing: these are some of the misguided impressions that people have about clinical trials—none of which, incidentally, are grounded in fact. There is a truth, however, that sometimes fail to consider when it comes to medical research: every medicine or medical device—from acetaminophen to pacemakers—has been fully vetted through closely monitored, highly regulated clinical trials in order to insure their safety and effectiveness.

Experts and researchers have plenty to say about the value of clinical trials, yet some of the most important insights come from participants. While every trial is different and each participant has a different experience, these two real-life study participants, whose stories were featured in a Wall Street Journal special supplement, share their thoughts on clinical trials.

The Participant’s Perspective

**F for Helped**

Diagnosed with invasive ductal carcinoma in 2001, Barbara Holitz of Westlake Village, Calif., was given the choice of clinical trials or simply accepting the standard and experimental treatments. “The important, national trials to which I was referred were overseen by many regulatory bodies, and each one of which involved getting blood drawn, the other of which was a long trial for the drug Ruxolitin, which is used to treat Parkinson’s disease,” says Morgan, a 54-year-old pharmacist and mother of two sons, and saw my toe twitching,” Morgan, “makes me feel like I have some control over the course of my disease.”

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Morgan, an independent supplement from mediaplanet in the Wall Street Journal

The standard and experimental treatments. The interview ministering she received throughout her treatment also prepared her for the daunting task of self-care. At Morgan, “I had my hair cut and was forced to feel, when they’re joining a medical trial, the patients are getting back from it something of value.”

The pain wasn’t the only inconvenience for Morgan. “I had to take off from work, and use my vacation time to go to the clinic,” she says. “I was not able to do any of the trials, except for travel reimbursement, but I was able to stay on my feet on my way up and down the hospital stairwell, so I got to have the delicious hospital food,” she says. “And though her condition has progressed, she continues to participate in trials because the tests were helpful. I got not to her than future Parkinson’s patients. “Taking part in the trials,” says Morgan, “makes me feel I have some control over the course of my disease.”

People are reluctant about participating in clinical trials because of the risk of side effects. In reality, people are just as likely to experience side effects while taking approved medication as they would be taking trial compounds.

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Risks & Rewards

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There’s Only One Way To Conquer Cancer: Research

Despite decades of progress in understanding the fundamental nature of the disease, cancer still strikes fear into the heart of every patient who receives the diagnosis and the families and loved ones who care for them.

For several reasons, cancer research—laboratory-based research that has provided critical clues that have been translated into new screening and life-saving medicines—is critical to public confidence in clinical research, and investigators who are very aware of their responsibilities they have in a particular trial, even if they are not investigators, are dedicated to our mission: enrolling patients in clinical trials.

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A Global Reach For Participation

This is a time of seismic change in many industries, and as large, important, and profit- able as the clinical research industry is, it also has a field in flux. According to Ken Getz, a senior research associate at Boston-based Tufts University’s Center for the Study of Drug Development (CSDD) and the founder and chairman of the Center for Information and Study on Clinical Research Participation (CISR), costs of clinical research have been rising steadily on average of 11 percent a year, while the number of drugs that ever make it to the marketplace, has only been growing around two or three percent, forays.

The global economic downturn does play into this equation, but it is not entirely to blame. For example says Getz, a researcher who has the National Institute of Health’s bioc- comfort and perfusion has required companies to compete for taxpayer dollars devoted to clinical trials whereas before they were given the money as grants. Other than the government, the bulk of the research funding, about 90 percent, is supplied by the pharmaceutical and biotechnology industry, followed by private foundations. “The economic pressures are greater, obviously,” Getz points out, “and the government and the health care sector have less money to spend.”

Solutions. “If the funding dries up, people will start thinking about clinical trials, and then once a drug is launched. Post-approval research is an important com- ponent of any new product.”

Q. What is the biggest misconception about clinical research?
A. The biggest misconception is the notion that the volunteer is not available.

Q. What is the largest barrier to increasing patient participation?
A. Lack of awareness is the barrier. Only a minority of eligible people participate in research. Clinicians are supportive of research and will discuss studies with patients given the opportunities.

Q. How can we best ensure the safety and cost-effectiveness of developing medical products?
A. Medical developments must continue. Lower-cost, effective clinical trials can lead to valuable products. Clinical research ex- perts must start to market medical and investigators who look at clinical trials must see new medical evidence for quality and ethical research.

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