MEDIA PLANET

Clinical Trials

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YOUR GUIDE TO UNDERSTANDING THE NEED FOR CLINICAL RESEARCH AND PARTICIPATION

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CLINICAL TRIALS

Publisher: Chrissy Sheehan

Contributors:
Ken Getz
Tyler Jacks, PhD
John Patrick Pullen
Judith M. Kramer, MD, MS

Editorial Manager:
Jackie McDermott
jackie.mcdermott@mediaplanet.com
Production Manager:
Carrie Reagh
carrie.reagh@mediaplanet.com

Printer: Dow Jones
Photos: ©iStockphoto.com

For more information about supplements in the daily press, please contact: Kayvan Salmanpour
1 646 922 1400
kayvan.salmanpour@mediaplanet.com

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1. ASK your doctor about ongoing clinical trials and how to participate.
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4. LISTEN to your local radio and READ your local newspapers for clinical trials going on in your neighborhood.
5. SEARCH key sites.
   www.clinicaltrials.gov: information about a trial's purpose, qualifications, locations, and contact information. A service of the US National Institutes of Health.
   www.searchclinicaltrials.org: an educational resource to educate the public about clinical research and participation sponsored by the Center for Information and Study on Clinical Research Participation (CISCRP).
   www.centerwatch.com: a global source of news, directories, proprietary market research, and analysis for clinical trials professionals and patients.
6. SPREAD the word!
   www.clickitforward.org: a health movement supporting medical research by inviting friends and family members via Facebook or MySpace.

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.

KEN GETZ
Founder and Chairman, CISCRP

Nearly 4,000 experimental drug therapies are in active clinical trials today and that number will continue to grow as improvements are made in detecting disease, in understanding the root causes of acute and chronic illnesses, and in discovering medical innovations. And in the not-so-distant future it will be more common for clinical trials to be discussed during routine visits with the doctor as electronic health records and clinical research converge.

At this time, for the vast majority of people, the idea of clinical trials never enters their consciousness. Most people stumble upon clinical trials when faced with the sudden prospect of a serious, often life-threatening, illness for which no marketed medication is available or adequate. Information about clinical trials may first come from a physician or nurse, friends and family, or a personal search on the Internet or in the newspaper. Regardless of its source, patients and their support network must gather information quickly in order to make major decisions about whether to participate. This rush to navigate the unknown terrain of clinical trials invariably feels like an overwhelming and confusing undertaking.

Having interacted with many patients who've been through this harrowing experience, in 2004 I founded the Center for Information and Study on Clinical Research Participation (CISCRP). This Boston-based independent non-profit is dedicated to helping raise public and patient awareness about clinical research. I also founded CISCRP to raise the level of public appreciation for clinical research participants. After all, behind every medicine and intervention are thousands of patients who have volunteered to participate in clinical trials.

There is a chance that participation may bring hope to the study volunteer. Yet, more often clinical trials will benefit those who will suffer from the illness in the future. And of course, our overall public health benefits from clinical trials regardless of whether an experimental treatment is safe and effective or is harmful and ineffective.

Participation is a courageous act as there are numerous risks in clinical trials. Even the best run studies are not completely free of risk despite the fact that the research process is highly regulated, managed by very experienced professionals and has many built-in safeguards to help protect study volunteers. It is important to know all of the facts about clinical trials before choosing whether or not to participate in one. At CISCRP, our motto 'Education before Participation' guides the many programs and initiatives that we implement each year to improve public and patient literacy, to engender feelings of empowerment and control among patients and their families, and to ensure more informed decision-making.

This special report also plays an important part in 'Education before Participation.' It is a reference resource offering an introduction to the clinical research process and to valuable sources for more information. This report also familiarizes the reader with the many professionals, lay people and patients that participate in clinical trials, and dispels and corrects some of the most common misconceptions 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 thanks and appreciation goes to the millions of medical heroes each year who give the gift of their participation to clinical research and the public's health.

Ken Getz is founder and chairman, CISCRP and author of The Gift of Participation and Senior Research Fellow, Tufts Center for the Study of Drug Development, Tufts University Medical School.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

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 US for coronary heart disease was cut in half.

A recent analysis indicated that although approximately half of this decrease can be attributed to reductions in major risk factors like cholesterol levels, blood pressure, and smoking, the other half is attributable to medical therapies validated in 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 therapies have been provided by pharmaceutical, biotechnology, and device companies. Without the contributions 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 public's trust in the pharmaceutical industry has been waning in recent years, however. Some people believe that clinical trials are unnecessary, profit-driven "experiments" conducted on humans. Such individuals would prefer their own doctors choose what therapy is best for them, rather than leave their treatment to the "flip of a coin." What these people may not realize is that doctors don't always know what treatment is best because objective comparison of large numbers of patients 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 offered 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 extra heart beats using anti-arrhythmic drugs would save lives in patients with coronary artery disease. Before the trial started, some attacked it as unethical because half the patients were not prescribed anti-arrhythmic drugs already commonly used by doctors. The trial surprised everyone by showing that patients treated with the anti-arrhythmic drugs tested were approximately three times more likely to die than patients receiving placebo therapy! The prescribing doctors thought they were helping, but these drugs had unintended consequences. As this example shows, clinical research is not always devoted to finding the next "blockbuster" drug, but also can contribute invaluable information about the benefits and safety of existing therapies, providing doctors and patients with reliable information for choosing between alternative treatments.

Many breakthroughs in disease prevention and treatment in the last half-century would never have come to pass had it not been for the willing participation of research subjects. In the 1950s, for example, parents were reluctant to allow their children into public swimming pools because of fear of contracting polio. A randomized trial of the Salk polio vaccine in over 600,000 school children led to the approval of the first preventive treatment for that disease. Together with the later addition of an oral vaccine, polio has been nearly eradicated in the US. Likewise, measles was nearly eliminated by a vaccine tested in clinical trials. People born after the widespread deployment of measles vaccine may not be aware that measles was not always a mild disease. Fatal outcomes and brain infection leading to permanent brain damage were uncommon but devastating complications. These diseases would still be a danger to America's children today were it not for clinical trials.

Another example of the societal benefits of clinical research can be found in a landmark trial of tuberculosis prevention in a remote community of 7,333 Alaskan natives conducted from 1957–59 by the US Public Health Service. Households were randomized to one year of blinded treatment with isoniazid or placebo. With 86 percent community participation, six years of follow-up showed an average reduction of 60 percent in new, active cases of tuberculosis. This trial (and its numerous participants) contributed to the scientific foundation for tuberculosis policies still adhered to today.

As these examples show, clinical trials are necessary for discovering important treatments and understanding counterbalancing risks, but they are only possible with widespread participation of research volunteers. The care of all Americans will be improved if patients receiving medical care are encouraged to participate in clinical trials.

Judith M. Kramer, MD, MS is executive director of the Clinical Trials Transformation Initiative (CTTI) and associate professor of Medicine, Duke University.

JUDITH M. KRAMER, MD, MS
editorial@mediaplanet.com

A Special Thanks To...

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AACR American Association for Cancer Research
ACRO ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS
Partnerships in Clinical Trials
DIA www.diahome.org
ASCO American Society of Clinical Oncology

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 trial—none of which, incidentally, are grounded in fact. There is a truth that people sometimes fail to consider when it comes to medical research studies: 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.

"Every drug that people have ever taken, vaccines that their children have taken, flu shots that they get, are all available because of the gift that other individuals have given by participating in clinical research," says Christine Pierre, president of RxTrials, an Ellicott City, Md.-based network of investigative sites.

Clinical trials vary widely due to the nature of the medications they test, but at their essence, they are sponsored by pharmaceutical companies and are conducted by research teams that include doctors and other medical professionals. Clinical trials are governed by strict protocols, and are overseen by many regulatory bodies, from the Food and Drug Administration (FDA) to small Independent Review Boards (IRBs).

"It's a very thoughtful process that people go through to develop drugs," says Steven Steinbrueck, president of Stonebridge GCP Consulting, a Newtown, Penn.-based consultant. "Before the first people ever get them, (drug developers) really have a feeling that this drug is safe and it's going to do what it's supposed to do."

In fact, says Steinbrueck, if a drug developer starts with an average of 5,000 possible formulas, they will throw away 4,990 compounds that they don't have confidence in. "Out of the remaining ten, only one makes it to market," he adds.

Clinical trials are typically conducted in four phases. Phase one is when generally healthy people are given the medication to test the ingestion of the pill or treatment will have no adverse, toxicological effect. Phases two and three dive deeper into the safety, effectiveness, and dosage of the medication, and it's after these stages when the FDA would approve the drug or device. Phase four examines new uses for previously approved treatments. For example, minoxidil was developed to treat high blood pressure but was found to reverse the effects of male-pattern baldness; it's now marketed under the name Rogaine.

It's important for participants to understand the many mechanisms that ensure the safety of the test subjects. Tests and studies are subject to strict regulations and guidelines through the FDA, Department of Health and Human Services and the Department of Health and Human Services. And each trial is monitored by Independent Review Boards (IRBs), a group of independent medical experts, ethicists, as well as lay people, to share the volunteers' perspective. Researchers report periodically to the IRB, outlining such things as contact with patients, the tests conducted, the results recorded and even the side effects reported. To ensure the safety of human subjects' it's important for IRBs to be accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). These safe guards are in place to make participation a safe experience, since as Pierre notes, "People who participate are giving the gift—they really are the heroes that are helping to develop the new drugs, devices, biologics, and treatments for the future."

> "It's important for participants to understand the many mechanisms that ensure the safety of the test subjects."

JOHN PATRICK PULLEN
editorial@mediaplanet.com

The Participant's Perspective

Experts and researchers have plenty to say about the value of clinical trials, yet some of the most important insight comes from participants. While every trial is different and each participant has a different experience, these two real-life study participants, whose stories were provided by the Center for Information and Study on Clinical Research Participation (CISCRP), offer valuable insight into real life in clinical research.

Faith Rewarded

Diagnosed with invasive ductal carcinoma in 2001, Barbara Holtz's first meeting at Boston's Dana-Farber Cancer Institute resulted with oncologists recommending she enroll in a clinical trial of the drug Herceptin. "Up to that point, Herceptin had been widely used to treat metastatic breast cancer," Holtz says. "This important, national trial was to test whether Herceptin could be effective and non-toxic to early-stage patients and possibly prevent their cancers from progressing."

Family members dissuaded her from taking part in the trial, saying she'd be better off with established treatments, while Holtz believed in how clinical trials contribute to scientific research. "I felt very threatened by this disease and I wanted to take aggressive steps to fight it," she recalls. Her faith was rewarded as the regimen she received as a result of participating in the trial included both the standard and experimental treatments. The intensive monitoring she received throughout her treatment also proved comforting as she battled various side effects. The trial was stopped early because of overwhelmingly positive results. "I'm glad I did it," Holtz says. "My message to others would be, have an open mind to being a clinical trial subject. Learn all you can about the trial's purpose and requirements and go for it!"

Taking Control

It all started with a toe twitch for Linda Morgan, a 54-year-old pharmacist and mother from Asheville, N.C. "I had my feet propped up on the chair and was talking to my two sons, and saw my toe twitching," she says. "I showed it to them and said, 'Hey, isn't that weird?'"

After a year of twitching and similar symptoms, Morgan went to the doctor in 2005, where she was diagnosed with Parkinson's Disease. She set out to take part in various clinical trials for Parkinson's Disease, and found a clinical trial at Duke University with the goal of finding a less expensive method for tracking certain neurotransmitters. Researchers worked around her schedule, and she had no side effects. That trial was easy, says Linda, as were the next two studies Linda found, one of which involved getting blood drawn, the other of which was a year-long trial for the drug Rasagiline, which is used to treat Parkinson's.

The next trial was a different story and much more uncomfortable. "I got stuck pretty much everywhere they could stick you," says Morgan, who was administered an IV and a spinal tap in a week-long on-site trial. "That trial was real invasive. It was painful and scary," she says. "I was real glad when it was over."

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 trial," she says. She wasn't paid for any of the trials, except for travel reimbursement. "The NIH paid for my flight up there and my stay in the hospital, 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, if not to her, than to future Parkinson's patients. "Taking part in the trials," says Morgan, "makes me feel like I have some control over the course of my disease."

Risks & Rewards

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.

"There is a risk with all medicines," says Liz Moench, the president of MediciGlobal, a Penn.-based patient recruitment firm. "When a risk is known, that risk has to be reported to the ethics board and to the investigators conducting the study so people are apprised of what information has surfaced about that product."

However, participants can experience several benefits when involved in clinical trials, such as new treatment options. "For most people, they're not satisfied with their current treatment," says Scott Connor, vice president of marketing for Penn.-based patient recruitment firm Acurian. "They're taking some sort of a marketed drug and they are not getting relief from it."

The primary reason that people learn more about their conditions is because clinical research trials build in a process called informed consent. "The informed consent process is about explaining the study, the medication, the risks, the benefits," says Moench. "It is an invitation to be a part of that dialogue. If you go in for conventional treatment, that isn't really part of your discourse at all," she adds.

Participation can offer increased access to health care. For example, says Moench, in a three year study of diabetes patients, volunteers received more than $15,000 worth of care. "The patients never knew how much it was, because the researchers cannot tell them," she says. "It can't be a reason to join the study."

"It has to be an equitable exchange," continues Moench. "The patient has to feel, when they're joining a medical study, that they are getting back from it something of value."

JOHN PATRICK PULLEN
editorial@mediaplanet.com

> "Participation can offer increased access to health care."

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 types of cancer, laboratory-based research has provided critical clues that have been translated into new life-extending and life-saving medicines. However, for others, such as pancreatic cancer and glioblastoma, still only a small percentage of patients live for a year after they are diagnosed. How can we do better?

The progress in cancer treatment that we have witnessed over the past few decades is rooted in research discoveries made largely in academic laboratories over the past 30 to 40 years, with the bulk of the funding coming from the federal government. These discoveries have revealed some of the multitude of complex changes that occur as a cell makes the journey from normalcy to malignancy. New cancer medicines like Gleevec and Herceptin work by counteracting the effects of certain of these changes and have provided dramatically improved outcomes for patients with forms of leukemia, stomach cancer, breast cancer and others. Today, using new tools and new technologies, the cancer research community is dramatically accelerating the pace of discovery. Novel cancer targets are emerging by the day and more familiar targets are finally starting to yield. We can now envision strategies to control major tumor types, to take the upper hand in the fight against cancer. But we must not lose momentum.

Excluding the recent, short-term infusion of funds from the stimulus package, funding from the National Cancer Institute over the past decade has failed to keep up with inflation. The success rates for grants have fallen to depressingly low levels and there has been a steady flow of talented investigators moving abroad to countries that have increased their investment in cancer research. More funding and more sustained funding for cancer research is a critical part of the solution. Without the necessary funds, the pace of research will slow; key discoveries will be delayed; and the implementation of new strategies to control cancer will take years longer than necessary.

While increased investment in cancer research is imperative, so too is a rethinking of how cancer medicines are developed. We must apply the best of science to the development and evaluation of new cancer drugs. We must move beyond overly large clinical trials that are designed to demonstrate only incremental improvements in survival. By extending the increasingly sophisticated understanding of the individual nature of cancers that have been borne from laboratory research to the clinical setting, it will be possible to design leaner and more effective clinical trials. Science-driven clinical trial should also reduce the high cost of cancer drug development, leading to more affordable medicines.

For those of us in the trenches of cancer research, the war on cancer has special meaning. For the thousands of investigators—from students to Nobel Laureates—who gathered at last week's Annual Meeting of the American Association of Cancer Research in Washington, there is a palpable sense of excitement about the prospect of delivering on the promise of years of dedicated effort to understand our common enemy. There will be no single solution, no magic bullet. But with proper support and with continued innovation in the laboratory and in the clinic, we will prevail.

Tyler Jacks, Ph.D., is the immediate past-president of the American Association for Cancer Research and the director of the David H. Koch Institute for Integrative Cancer Research at the Massachusetts Institute of Technology.

TYLER JACKS, PHD
editorial@mediaplanet.com

Ethics & Objectivity: A Clinical View

Cynthia Sinsel has a unique perspective on the ethical issues surrounding clinical research. A project manager for Dallas-based MedTrials, Sinsel has been a part of many trials, but in two studies she had another role—a participant.

Nine years ago, Sinsel was diagnosed with aggressive non-Hodgkin's lymphoma, a cancer that she has since overcome, and as a result she is taking part in both a quality of life clinical trial and a metabolic study. "They're going to be following me for many years because I was so very sick and they want to see why I got so well, so quickly," she says.

The experience has given Sinsel a unique perspective into the ethical issues of clinical research. "(Research Professionals) are here on behalf of the advocacy of the vulnerable," she tells researchers she trains. "And (participants) are vulnerable just by virtue of being in a clinical trial."

The fundamental ethical issue at the core of clinical research, says Sinsel, is balancing unbiased observations with the care of the people lending themselves to the trial. That dilemma can manifest itself in many ways. Many researchers think of it as a balance of risk versus benefit.

Currently, an issue facing the industry is clinical research conducted in developing countries. "The ethical misperception is that there is this kind of 'cut and run' where big pharma goes to a developing country to get whatever they need to get to further their corporation," she says. But this is rarely the case, says Sinsel, because researchers improve the standard of care in these areas by giving medical training, leaving behind valuable equipment, and forming partnerships with communities. "If a company leaves," she says, "they leave a bit of themselves behind."

Clinical research isn't completely selfless—sometimes gravely ill people participate in trials to get relief where other treatments have failed. Cutting off that treatment is a difficult issue for researchers and one that can be averted through what they call "compassionate use trials," where patients continue getting treated in return for prolonged testing. "Other lives may breathe easier because a person like me gave of themselves (as a participant in) a trial," says Sinsel. "I'm a biologist, but the bio is what I do. The ethics is who I am."

JOHN PATRICK PULLEN
editorial@mediaplanet.com

Clinical Researchers: True Professionals

In clinical trials, researchers use the scientific method—that tried and true set of procedures that has guided innovators since the seventeenth century—to ensure the professionalism of their work.

But just as important as this plan of action are the people who execute it, skilled biologists who give bear responsibility for the entire industry. "Well trained, educated, and competent clinical researchers who are very aware of their obligations to faithfully follow protocols and regulations around clinical trials are critical to public confidence in clinical research," says Richard Day, the director of clinical pharmacology and toxicology at St. Vincent's Hospital in Sydney, Australia, and a member of the faculty of medicine at Australia's University of New South Wales.

According to Day, while a clinical researcher's qualifications depend on the responsibilities they have in a particular trial, each investigator should have some sort of official accreditation. For example, chief and associate investigators need a post-graduate degree in the health sciences and often medicine. If they were conducting research in the U.S. or in Europe, they would have board certification in a medical specialty. "Increasingly, investigators are encouraged to gain specific knowledge and training and sometimes accreditation to undertake clinical research," says Day. "This is an important and welcome trend that is occurring world wide."

Universities are starting to offer degrees in regulatory science and drug development with components directly relevant to clinical researchers, says Day, but the professional standards don't stop there. According to Dr. Greg Koski, an associate professor of anesthesia at Massachusetts General Hospital, "Clinical research is a professional activity and the tools of professionalism, such as certification of individuals and programs that are specific to the jobs and tasks they perform, is a critical part of not just maintaining but improving safety and efficiency, as well as quality of the work that's done."

Koski also serves as a member of the board of the Association of Clinical Research Professionals and the president of the Academy of Pharmaceutical Physicians and Investigators, two groups currently working to establish certification standards within the industry. "We believe the time has come to improve the quality, efficiency, and safety of clinical trials by creating a global network of fully professional sites that all are operating under agreed standard operating procedures," he says.

JOHN PATRICK PULLEN
editorial@mediaplanet.com

Professional Spotlight

Panel Of Experts

LINDA G. STRAUSE, PHD
Executive Director
Oncological Clinical Operations
Vical Incorporated

Q. How can we best ensure the safety and cost effectiveness of developing medical products?
A. In order to ensure both safety and cost effectiveness, a detailed risk to benefit analysis must be performed. The potential risk to potential benefit must include a detailed evaluation of pre-clinical and early phase studies, effective and timely monitoring of the data, including adverse events, and evaluation of the experience of the investigator/physician and staff and the appropriateness of the facility and its resources. Certification and accreditation programs will provide needed documentation. Protecting human subjects is paramount.

Q. What is the biggest misconception about clinical research?
A. The biggest misconception is the notion of the subject as a "human guinea pig." Without those individuals who participate in clinical research new products would never become available to treat diseases. The public must be educated and provided with information so they can understand a given study in order to make knowledgable decisions.

MYRL WEINBERG
President
CAE, National Health Council

Q. What is the largest barrier to increasing patient participation?
A. Individuals simply aren't asked. Many organizations have done outstanding work to educate people about the importance of participating in clinical trials. We need greater support from both the public and private sectors to encourage participation.

Q. How can we best ensure the safety and cost effectiveness of developing medical products?
A. The National Health Council represents the more than 133 million Americans with chronic diseases and disabilities. People place great hope that science can produce break-through treatments. Unfortunately, new discoveries are judged by old regulatory science. These new drugs that address unmet needs today become the lower-cost generic medicines of tomorrow.

Q. What is the biggest misconception about clinical research?
A. Clinical research is not just about the sick. We need more people—including people in good health—to participate in clinical trials. The core objective is the greater public good of expanding knowledge, not just finding new treatments or cures.

ANITA KABLINGER, MD
Director, Pscyhopharmacology
LSUHSC Schreveport

Q. What is the largest barrier to increasing patient participation?
A. Lack of awareness is the barrier. Only five percent of eligible people participate in research. Clinicians are supportive of research and would 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 exposure must start in medical training and investigators who lead clinical trials must meet educational requirements, possessing humanitarian incentive for quality and ethical research.

Q. What is the biggest misconception about clinical research?
A. The largest misconception is that the voluntary experience is negative. Satisfaction surveys of participants in clinical research illustrate study preference over routine clinical care. Participation in research does not mean you are an "experiment." A research volunteer is the future of health care.

RICHARD L. SCHILSKY, MD
American Society of Clinical Oncology (ASCO)
Immediate Past President

Q. What is the largest barrier to increasing patient participation?
A. A critical barrier is that many patients may not be informed about opportunities to participate in trials and potential benefits. Also, many patients don't know that clinical trials are an important treatment option and not a last resort. Doctors must invest the time and effort required to provide clinical trials to their patients, and need adequate reimbursement to do so.

Q. How can we best ensure the safety and cost effectiveness of developing medical products?
A. By conducting well designed and conclusive clinical trials that prove the safety and effectiveness of new treatments compared to standards of care.

Q. What is the biggest misconception about clinical research?
A. Not everyone realizes that the best patient care is often provided through a clinical trial and the only way that real progress against cancer is made. In fact, every cancer treatment that is available to patients today is the direct result of a clinical trial where a new treatment was proven better than the current standard of care at the time.

JOSEPH HERRING
Chairman and CEO
Covance

Q. How can we best ensure the safety and cost effectiveness of developing medical products?
A. A more recent improvement in R&D productivity involves earlier safety and efficacy testing, which allows the industry to determine whether a new drug candidate has real potential before making large investments in clinical trials. Patient safety is the highest priority and it doesn't stop once a drug is launched. Post-approval safety monitoring is an important component of verifying the long-term safety of a new medicine.

Q. What is the biggest misconception about clinical research?
A. Unfortunately, the role clinical research plays in bringing a new medicine to market is not readily understood. Most people see the end result, a small pill for example, but what they miss is the medical information derived from hundreds of trials involving thousands of patients. Efficacy and safety are assumed, but these precious conditions were built over a long period of time under rigorous and heavily regulated conditions.

A Global Reach For Participation

This is a time of seismic change in many industries, and as large, important, and profitable as the clinical research industry is, its also a field in flux.

According to Ken Getz, a senior research fellow 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 (CISCRP), total spending on clinical research was nearly $94 billion in 2008, and spending had grown 6.9 percent annually the prior eight years. But growth has been slowing due to a confluence of factors. "Over the last three to five years, the cost of drug development has been rising steadily on an average of 11 percent a year, while the sales of drugs, once they enter the marketplace, has only been growing around two or three percent," he says.

The global economic downturn does play into this equation, but it's not entirely to blame. For example, says Getz, a change in how the National Institute of Health has decided to fund research has required groups to compete for taxpayer dollars devoted to clinical trials whereas before they were given the money as grants. Other than the government, the lion's share 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 foundations and the government have less money to spend," says Beth Harper, the chief clinical officer for Upper Saddle River, N.J.-based Centerphase Solutions. "If the funding dries up, people are forced to rationalize their spending in different ways or start looking at getting smarter about the way they're executing the trials to quickly get the decisions either to fail fast or to move a product forward." Greater than the challenges of funding is having patient access, which means studies run quicker and researchers can reach faster conclusions about continuing the development or moving on to the next compound. The need for participants has spread researchers into global markets. However, hospitalization costs are much less outside North America, a side effect of conducting trials on participants outside the U.S. "Over the last five to seven years, more sponsors of drug studies have looked at regions around the world that are less expensive relative to the traditional North American and Western European environments," says Getz. And those researchers include the federal government. "Today, over half of the studies that are overseen by the Food and Drug Administration are conducted in North America," he adds. And while it's easy to point to increasing profitability as the main reason for taking these trials off shore, it's really about doing more—finding new cures and better treatments—with less. "The economics of research at the macro level is pretty intense," says Getz. "There's a lot of pressure being placed on research professionals to be sure they're doing their work as efficiently as possible."

JOHN PATRICK PULLEN
editorial@mediaplanet.com