The development of advanced medical treatments has been halted by outdated public perception. It’s time to shift perspective.
It is said that the greatest gift is one that is given anonymously. Millions of people who volunteer to participate in clinical trials each year give this unique gift.

Pushing the frontline
These courageous individuals are rightly considered by some to be medical heroes. Their profound gift of participation helps advance our collective health.

Volunteers help researchers explore promising new medical treatments targeting the cause of illness, relieving the symptoms of disease and improving the human condition. Every medicine you take, including over-the-counter and prescription drugs and medical devices, would not be available without medical heroes and the clinical trials in which they participated.

Different discoveries
Every person’s decision to participate is different. In every case, there are risks involved. For someone with a serious illness like cancer, participation may provide access to a new potentially life-saving treatment. Someone with a chronic illness like Parkinson’s disease might participate to offer hope for future patients fighting against the disease. Some choose to participate as healthy volunteers to help research professionals identify new and safe medicines to begin testing among patients. Anyone can volunteer to participate. And, with more than 80,000 clinical research studies conducted annually, there are many opportunities to participate and contribute to the process. There are many different types of clinical trials, so the experience of participating will vary.

In some studies, participants may take an experimental study drug so researchers can assess whether that drug is safe and effective. Some studies involve the collection of tissue samples; others look at behaviors such as diet and sleeping patterns. Some studies involve filling out a survey.

On behalf of researchers and patients, I thank the millions of medical heroes who bravely give the gift of participation every year and play an essential role in the development of new medical treatments.

Ken Getz
Founder and Board Chair, Center for Information & Study on Clinical Research Participation (CISCRP)

Grounding perspective
The profound decision to participate may bring hope to the individual participating, but often it does not. Still, something new is always learned from each clinical study. The gift of participation always benefits public health and advances medical knowledge because it helps researchers and doctors learn about what works and what doesn’t work in treating illnesses and conditions.

On behalf of researchers and patients, I thank the millions of medical heroes who bravely give the gift of participation every year and play an essential role in the development of new medical treatments.
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Who Are Our Clinical Research Professionals?

Raising public awareness of clinical trials is the focus of many initiatives, yet by and large the people who carry out clinical trial operations remain unsung.

Clinical trials serve a critical role in improving health care by answering important questions about the safety and effectiveness of new drugs, devices and treatments that, if proven safe and effective, are made available to the public.

Behind the curtain
The oft-overlooked individuals who carry out clinical trial operations, clinical research professionals, have largely remained hidden in the background—even unfairly typcast as “mad scientists,” which could not be further from the truth.

Clinical research professionals are most often doctors, nurses or allied health professionals who dedicate their careers to a higher purpose: that of discovering and proving new therapies that improve lives and may ultimately lead to cures for the various diseases that claim the lives of those we love.

Earning stripes
Clinical research professionals have specialized training in Good Clinical Practice, the international ethical and quality standard for clinical trial conduct. Many have earned certification as specialists in clinical research, an achievement demonstrating an ongoing commitment to excellence, professionalism, ethical behavior and patient safety.

Those who are members of professional organizations such as the Association of Clinical Research Professionals (ACRP), the Academy of Physicians in Clinical Research and the Academy of Clinical Research Professionals commit to, and are held to, a code of ethics. They also hold themselves accountable for continuous improvement by actively developing their professional competencies.

Education is essential
The importance of public confidence in clinical research and the people behind it cannot be overstated. Without public confidence, without trust from the patients who volunteer to participate in research studies, clinical trials and their resulting medical advances cannot occur. This is why ACRP, a non-profit organization supporting the growth and development of 13,000-plus clinical research professionals, is committed to helping build that trust by working to ensure clinical research is performed ethically, responsibly and professionally everywhere in the world.

What does that mean to the public? It means you can trust that clinical research professionals are just that: professionals. They take their obligations to you and the work they do every day seriously in hopes of continuously improving health care and quality of life for all.

By Jim Kremidas, Executive Director, Association of Clinical Research Professionals

Throwing Your Hat in the Ring?

Every day Americans decide to take medicines and try prevention and treatment options, based on health care providers’ recommendations, which are often informed through clinical trials.

While we might notice that a medicine’s label says “for adults ages 18-55” or “do not take with grapefruit,” for example, we’ve probably never thought about how researchers study medicines or discover which medical practices were best and for whom.

Grounding procedure
The National Institutes of Health (NIH) explains: “Clinical trials are research studies exploring whether a medical strategy, treatment or device is safe and effective for humans. These studies also may show which medical approaches work best for certain illnesses or groups of people.” None of this knowledge would be possible without research volunteers.

Who can and should participate in research? The answer is everyone. Our country is very diverse. If people like us don’t participate in research, then the results of research may not apply to people like us. It is important that we learn more about treatment and prevention options in all types of people to ensure the best health outcomes for everyone.

More involvement
It is also important that we learn as rapidly as possible. Answers are often delayed because of the time it takes to find research volunteers.

You do not have to be a certain age or be sick to participate in research. Studies are open to volunteers of all ages. Some studies are as simple as answering a short questionnaire about diet, behavior or growth. Other studies may look more in-depth at a person’s genetic makeup, environment and health outcomes or require doctor visits to follow a person’s medical condition over time.

Where to turn
Volunteers can register to learn about research opportunities to participate in a clinical trial by entering key terms related to medical conditions, treatments or personal characteristics into the search feature.

There are also opportunities to help design clinical trials in partnership with researchers, which are most commonly offered by health advocacy organizations or doctors working at academic medical centers.

The bottom line is that research needs us! In order to more rapidly answer questions that improve and save lives, researchers need people and data to study and each of us are eligible to provide it. Please take the time to check out your options online, or ask your doctor about how you can volunteer to get involved with research.

By Matthew Harker, Bray Patrick-Lake, Leanne Madre, Pamela Tenaerts, Clinical Trials Transformation Initiative
What Can Organ Donation Teach Us About Clinical Trials?

As Americans clamor for new treatments for cancer, Alzheimer’s and rare diseases, few individuals recognize the role that they themselves could play.

Not enough Americans enroll in clinical trials, unknowingly stagnating the very medical advances they hope to see. To increase enrollment, the United States must increase awareness.

Not enough takers
Clinical trials are a critical part of the Food and Drug Administration’s approval process for new therapies. Yet the Tufts Center for the Study of Drug Development reported that 37 percent of clinical trial sites fall short of their enrollment goals, while 11 percent fail to enroll even a single patient.

Enrollment struggles in part because patients lack awareness. One study found that 40 percent of adults did not fully understand the idea of a clinical trial. Current or former trial participants may offer little help in this regard; roughly 88 percent of them rarely talk about their experiences after the trial concludes.

Repeating history
For policymakers, this challenge has a familiar ring. The United States faced another high-impact public health quandary several decades ago with organ donation. At the time, scientific advancement offered life-saving opportunities for patients needing organ transplants, but donors failed to materialize in sufficient numbers.

Congress, the Department of Health and Human Services and the Ad Council sprang into action with a multi-prong public awareness campaign to open Americans’ eyes to the need for donors. An array of public-private partnerships formed to support the initiative. “Share your life. Share your decision.” became a familiar call to action. Today, nearly 47 percent of Americans are registered organ donors.

The watermarks of the clinical trials challenge are much the same. The issue impacts Americans across ethnic, gender and socio-economic lines. All suffer when medical innovation is hampered; all benefit when it thrives and new therapies are discovered that improve and prolong life.

The cause of clinical trials would likewise benefit from a federal public awareness campaign. To spur medical innovation and facilitate discovery, patients must enroll in clinical trials. But first they must understand what purpose trials serve, how they work and what benefits they bring to a society where too many patients suffer with too few options.

By Anna Molinari, Clinical Trials Specialist
Doc Talk: Testing New Treatments for Cancer

To learn how clinical research is expanding our understanding of medical treatments, we chatted with an industry expert to get the facts.

What role do clinical trials play in medical research?

Clinical research and the participation of qualified subjects are necessary for the approval of new treatments by the FDA. They are vital to the progression of medicine. For example, I’m currently involved in clinical research for non-Hodgkin’s lymphoma (NHL), a type of cancer that starts in the body’s immune system.

Why are trials important in advancing the treatment of non-Hodgkin’s lymphoma?

Currently, only 30 to 40 percent of lymphoma is curable. Our goal is to get to 100 percent. I’ve participated in multiple phases of clinical trials in standard treatment, as well as novel treatments for lymphoma. Clinical trials help all patients with lymphoma, and they advance our knowledge of the condition and its potential treatment.

What should a person consider before enrolling in a clinical trial?

The decision to participate in a clinical trial is a very personal one. I suggest doing your research to understand the opportunity—who is sponsoring the trial and what is being studied. Discuss the decision with your loved ones. It could be an opportunity to gain access to novel treatments that are not yet available to the public. You’ll also be helping to advance science and contributing to important research that will aid future generations.

Clinical trials are helping cancer patients of all ages to travel, work and find a better balance within their new ‘normal.’

Nine years ago, Rebecca went to the emergency room with appendicitis-like pains. CT scans revealed that she had a tumor the size of a grapefruit sitting on her ovary. She was diagnosed with late-stage ovarian cancer, which has a five-year survival rate of 39 percent.

“It was like a big baseball bat to the stomach when you find out you have cancer. The fear of the unknown is intense,” recalls Rebecca. “You think, is life over? ”

Finding a trial

After receiving her diagnosis, Rebecca had surgery and chemotherapy, yet cancer cells remained in her body. Up to that point, Rebecca had heard of clinical trials but didn’t know much about them. Based on her doctor’s recommendation, she decided to enroll as part of her cancer treatment and to contribute to medical research.

The trial involved taking four pills a day and receiving a 30-minute infusion of drugs every two weeks. The experience, which included a few more doctors’ appointments, became part of her daily routine and the information gleaned from the trial not only proved valuable to her—it will likely benefit others moving forward. Rebecca is managing her cancer and has resumed her ‘normal’ routine of going to work, traveling and jogging. Her story demonstrates that volunteering for clinical research to improve treatment of disease and quality of life is often a very positive experience. She hopes more people will listen to the recommendation of physicians as they educate patients about the benefits of participating in clinical trials.

Setting the stage

Rebecca is not alone. More than two-thirds of Americans (72 percent) say it is likely they would participate in a clinical trial if recommended by their doctor, but only 22 percent say a doctor or other health care professional has ever talked to them about medical research, according to a recent, national public opinion poll. The poll findings underscore the role of health care providers in addressing concerns among patients and debunking myths that have contributed to a degree of skepticism and low participation rates.

When asked if they or someone in their family have ever participated in clinical trials, only 15 percent of non-Hispanic white respondents said yes, and the percentage is similarly low for minority groups (17 percent of Hispanics, 15 percent of African-Americans and 11 percent of Asians). Physicians play a critical role in informing patients about clinical research, but it is especially important that patients take the initiative to ask about participation in a trial.

Everyone who cares about the future of health—every stakeholder, from patients and family to academia to industry—has the responsibility to step up to change public perception of clinical research and make participation in research a health behavior that all Americans can embrace. As technology evolves, mobile apps and other devices can be useful tools to encourage more people to volunteer. Substantive conversations on clinical research in-person or on digital platforms can be a life-changing experience. Just ask Rebecca.
“I live from day to day in the hope that there’s something waiting around the corner”

Clinical trials have the potential to improve the outcome for patients like Melanie. Talk to your doctor if you would like to learn more about clinical trials or visit ciscrp.org.
A GIANT THANK YOU TO THE STUDY VOLUNTEERS AND PROFESSIONALS WHO PARTICIPATE IN CLINICAL RESEARCH EACH YEAR.

We’re grateful to each of the millions of medical heroes who help advance our knowledge about disease and conditions and influence how to treat them. For more information about clinical research, please visit CISCRP.org.

A sincere thanks to all the medical heroes from these sponsors: