

Guide to Advancing Medicine Through Clinical Trial Participation

Clinical Trials

Mel and Aaron Havert

One family shares how they tackle clinical trials as a unit and take care of each other through the journey

CISCRP founder Ken Getz on the everyday heroes who lie at the heart of medical innovation

The healthcare innovator taking a holistic approach to clinical research



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Clinical trial participants help make medical breakthroughs possible for people of all backgrounds. Learn how you can get involved at PfizerClinicalTrials.com/BeRepresented3.



Clinical Trial Participants' Selfless Gift to Medicine

By volunteering to participate in clinical trials of new and experimental treatments, medical heroes give society valuable knowledge about the nature of disease, its progression, and how — and how not — to treat it. Participation always carries some risk, offers some hope for a treatment, and even offers some hope for a cure, but it is likely to bring no direct personal benefit to those who volunteer. As such, medical heroes ultimately give a gift that will benefit future generations of patients.

Facing the challenge

For the vast majority of people, clinical trials are an abstract concept that have little to no personal relevance. Most people take a hard look at clinical trials for the first time when facing the sudden and often unexpected prospect of a serious and debilitating illness for which no medication is available or adequate. Typically, patients, their families, their friends, and their healthcare providers must gather information quickly to understand how the clinical trial process works, the requirements of participation as defined by the study protocol, and whether participa-



Every year, millions of people take part in clinical trials and become partners in the process of developing new medical treatments. We call these individuals medical heroes because they are ordinary people like you and me who have chosen to give the extraordinary gift of their participation.

tion is appropriate. This rush to navigate and master the unfamiliar terrain of clinical trials invariably feels overwhelming and confusing, and once in a clinical trial, many volunteers find the requirements and demands of participation difficult to manage.

Raising awareness

In 2003, the Center for Infor-



Ken Getz
Founder and
Chairman, CISCRP

mation and Study on Clinical Research Participation (CISCRP) was founded to provide outreach and education to those individuals considering participation in clinical trials and their support network. Based in the Boston area, this nonprofit organization serves the global community of patients and the public by raising awareness and providing

education about clinical trials and by enhancing study volunteer experiences during and after clinical trial participation. Our many events and services are designed to improve public and patient literacy; to engender feelings of empowerment and control; to ensure more informed decision-making, improved convenience, and accessibility; and to recognize and appreciate the medical heroes that inspire us.

This special USA Today supplement also plays an important part in raising awareness and literacy. It is a reference resource offering an introduction to clinical trials and providing valuable information to help you and your support network navigate the participation process.

At the present time, nearly 6,000 experimental drugs and therapies are in active clinical trials, and that number continues to grow as improvements are made in detecting disease, discovering new medical innovations, and understanding and addressing the root cause of acute and chronic illnesses. At the very heart of all of this promising, lifesaving, and life-altering activity are medical heroes to whom we owe our deepest appreciation for their profound gift of participation. □

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How African-American Men Can Beat the Odds Against Prostate Cancer



While prostate cancer is a concern for every middle-aged man, African-American men should be more concerned than most.

"The incidence of prostate cancer is over 60 percent higher in African-American men compared to white men, and in terms of mortality, it's 150 percent higher," says Thomas Farrington, founder and president of the Prostate Health Education Network (PHEN). "For African-American men, there are issues with treatment, access to treatment and quality of treatment."

A voice of reason

Farrington was diagnosed with prostate cancer in 2000 and, while now cancer-free, he has dedicated himself to making sure black men learn more about this deadly disease.

"I'm a 17-year survivor, and I know that the knowledge of these factors is one of the most crucial things in reducing mortality," says Farrington, who wrote the book "Battling the Killer Within" about his experiences.

How we test

While the prostate-specific antigen test is a non-invasive blood test, not every doctor or

insurance carrier makes the test a required part of annual check-ups.

"There's debate about when men should be tested and who should be screened, and that debate causes a lot of confusion," Farrington notes that African-American men tend to be diagnosed earlier in life, but men between age 55 and 70 "are very much at risk."

Volunteers needed

One factor in the high mortality rate for African-American men is likely their lack of inclusion in clinical trials. "There are a lot of trials in which African-American

men are not included, or not included in numbers that would be significant," says Farrington. "There are two pieces," he adds, regarding the oversight. "African-American men aren't educated about clinical trials and their potential benefits as a treatment option, and the scientific community hasn't approached this group as aggressively as they could."

Looking into clinical trials after a cancer diagnosis can be overwhelming, which is one issue Farrington addresses through the PHEN website. "Many men haven't been asked to join a clinical trial, and it hasn't been discussed by their

doctors," Farrington says. "We need to get the African-American medical community up to speed and engaged with clinical trials, and make sure the entire African-American community understands the need to engage."

While the incidence of prostate cancer in African-American men is still disturbingly high, Farrington is optimistic. "The mortality rates are declining faster for black men than white men at this point," he mentions, "and given how much higher they are, that's a good thing." ▣

Liane Bonin Starr

One Family's Journey Through Chronic Illness and Clinical Trials

The Havert family is taking on a major health diagnosis and taking care of each other along the way.



PHOTO: FRED GREAVES PHOTOGRAPHY

Aaron Havert, 40, and daughter Eleanii, 9, both have Hemophilia A, a genetic bleeding disorder caused by a lack of blood clotting factor VIII. The main symptoms of Hemophilia A include prolonged bleeding and bruising. Aaron's case is considered severe while Eleanii's case is considered mild. There's no cure for Hemophilia A, but gene therapy may help reduce the severity of the disorder.

Aaron, who was diagnosed when he was 10 months old, needs to prevent a spontaneous bleed from occurring. He treats his Hemophilia A with factor infusions administered directly

into a vein at home every two to three days. Eleanii receives factor treatment on demand, meaning she's treated when she has a bleed.

Caregiving and advocacy

Melanie Havert, Eleanii's mother, is a caregiver to both her daughter and to Aaron. The family lives in Northern California with their older daughter Charlii, age 11, and three pets.

Melanie, 36, started her caregiver journey in 2004 when she first met Aaron. He taught her at his kitchen table how to infuse him with life-saving intravenous injections.

"According to both Aaron and Eleanii, I am the best at giving infusions," she says.

"Without the factor being administered into their veins, Aaron would die, and Eleanii would have a very painful life and could even lose her life in the case of something like a minor head injury."

Melanie's caregiver role also includes giving Eleanii subcutaneous injections into her thighs; ordering medication and supplies; and attending appointments, conferences, and support groups. She's often a resource for other new caregivers.

When she realized how little information was available about female Hemophiliacs like her daughter, she committed to connecting with female symptomatic carriers of the disorder.

Melanie is also a project manager at Rare Patient Voice, a market research recruitment firm providing patients and caregivers with opportunities to share their opinions and experiences with researchers.

"I love helping others learn how to advocate for themselves and their families," she says. "We need to learn how to stand up for ourselves and voice our needs and desires when it comes to our health, our struggles, our wins, and our needs."

Clinical trials

Aaron has participated in five clinical trials over the past 30 years, including four for different anti-hemophilic factors

(AHF) and one for a first in-human gene therapy trial.

He participates to help improve treatment for Hemophilia. The condition can be difficult, causing physical limitations, chronic pain, and very expensive medical costs. His monthly medication costs \$20,000.

"There has been such a dramatic change in the medical treatment of my condition over the past 35 years, that the quality of life — and the longevity of life — for Hemophiliacs has so greatly improved," he says. "It is a testament to how important clinical trials and medical research are."

A better future

When considering participating in clinical trials, Melanie advises patients and their families to understand the risks, ask questions, and speak with others who've participated to gain a better understanding of the process.

She also advises preparing the family for all possible outcomes and discussing it as a unit. A clinical trial has the potential to affect the entire family. When Aaron wants to participate in a clinical trial, he and Melanie have a long discussion of the possible risks. If he decides to participate, he writes a personal letter to each of their daughters explaining exactly why he decided to participate and what he hopes will come out of it.

"Participating in a clinical trial is a big deal," says Aaron. "It is an act of love and hope for a better future. Without those willing to participate in clinical trials, medicine and the medical field would not be where they are today." □

Kristen Castillo

As the number of people struggling with Alzheimer's continues to rise, researchers are working overtime in hopes of finding a cure — but they can't do it alone.

An exciting development

"There are approximately 100 drugs currently being tested," explains Jeffrey Cummings, M.D., the director of the Cleveland Clinic Lou Ruvo Center for Brain Health. "About a third are in the advanced phases of testing. Some are promising enough that we believe a preliminary treatment would be available within five years."

The potential new drug aducanumab has been shown to remove the build-up of the Alzheimer's protein amyloid in the brain and slow the decline in memory and thinking skills

Are Scientists On the Verge of an Alzheimer's Cure?

in patients. Additionally, the Global Alzheimer's Platform Foundation (GAP) is working to reduce the time and cost of trials. GAP president John Dwyer explains, "The key to shortening clinical trials is recruiting people. We're in a chronic shortage."

Understanding the cost

By 2050, the cost of Alzheimer's disease in the United States will be \$1 trillion dollars, annually.

"No government can

absorb those kinds of costs," says Cummings. "Although research is expensive, it's hugely less expensive than the cost of caring for all these patients."

Malack-Ragona notes, "A person with dementia or Alzheimer's usually costs the system three times more than any other disease process."

Support and prevention

Caregivers, usually women, bear the major impact of Alzheimer's. "It affects them at

home, in their relationships, and at work," says Dwyer. "The caregiver's burden is uncharacteristically heavy and long in duration." Alzheimer's support groups, however, can ease the stress. Malack-Ragona reminds caregivers to "never stand alone" during the journey.

While Alzheimer's can't be prevented, reading, working puzzles, volunteering, and learning new things can lower risks. Proper nutrition and regular exercise are also

encouraged, along with avoiding cigarettes and getting enough sleep.

A change in awareness

Cummings acknowledges, "There's the idea that having a loved one who's confused is a shameful thing. Many families feel the need to hide it. That's a stigma we'd like to remove." Adds Dwyer, "We should embrace the fact the disease exists, learn how to reduce risks, and get involved in finding a cure."

Roughly 5.5 million Americans are battling Alzheimer's. The number could rise to 16 million by mid-century. A first-of-its-kind smartphone app will provide information about research trials, starting in June. The first person cured of Alzheimer's will likely be a clinical trial participant. ▣

Cindy Riley



"I have been a part of something that could one day change the lives of many people."

—Israel, clinical trial participant and community advisory board member

Listening and learning

Community contribution is key to meaningful research, and here at Biogen we're committed to amplifying diverse voices in the clinical trial space.

When you take part in a clinical trial, you're helping to represent your family, friends, and entire community. And when everyone is represented, we can better develop potential medicines for all.

Visit biogentriallink.com to learn how you can contribute to the greater good of medicine.



Otsuka's Holistic Approach to Clinical Research

Clinical trials are an essential part of scientific research and healthcare discoveries.

Global holistic healthcare company Otsuka Pharmaceutical Development and Commercialization, Inc. (Otsuka), is committed to developing new treatments in neuroscience, nephrology, and digital innovation with a focus on mental health.

Otsuka has been dedicated to discovering unconventional solutions for complex, underserved medical needs for over 30 years. Their neuroscience work focuses on treatments for adults with schizophrenia and major depressive disorder (MDD), and

neurological and neuropsychiatric conditions, such as Alzheimer's and posttraumatic stress disorder (PTSD).

"At Otsuka, we respect the value within every mind," says John Kraus, M.D., Ph.D., VP clinical development CNS at Otsuka. "That's why our clinical development in this therapeutic area will continue to address the gaps in mental health treatments, so those affected by CNS disorders can have more options to meet their needs."

Participation

Otsuka believes patient conversations with their doctor about clinical trials should be the standard of care.

When patients participate in trials, they're helping find solutions to complex healthcare challenges. Trials establish the safety and efficacy of potential therapies, as well as provide scientific data for the regulatory approval required to make treatments available broadly.

Clinical trials are a partnership between the volunteer, research physician and company sponsoring the trial. Constant communication informs the safety and efficacy of the product under research, always putting patient safety first.

Diversity, equity, and inclusion

Otsuka believes equitable

access to clinical trials needs to be a priority.

"We're focusing on activities that can begin to address clinical trial diversity and health disparities in the diseases we treat," says Sabrina Mays Diagne, senior director and diversity, equity, and inclusion officer. "Proposed interventions will help overcome barriers including medical mistrust, eligibility, enrollment practices, and access to information."

To accomplish this, Otsuka's Research and Development team has identified key priorities impacting the entire R&D ecosystem, including employees, vendors, sites, healthcare providers, and patients.

Holistic approach

Otsuka's holistic approach focuses on the whole body. By working to meet patients' unaddressed medical needs, they're poised to create new therapeutic approaches, products, and unprecedented drugs. ▣

Kristen Castillo



Find more information on Otsuka's ongoing, enrolling clinical trials, including PTSD, (MDD), Alzheimer's agitation disorder (AAD), binge eating disorder, and autism spectrum disorder (ASD).

Bringing Type 1 Diabetes Screening to All

Approximately 40-60 percent of people in the United States present with life-threatening diabetic ketoacidosis (DKA) at the time of a type 1 diabetes (T1D) diagnosis. There is a way to change that, however.

DKA is scary. It is a major and life-threatening complication due to a shortage of insulin, causing symptoms like dehydration, nausea, vomiting, confusion, or, in extreme cases, death. Luckily, JDRF-funded scientists have discovered how

to identify at-risk individuals prior to a T1D diagnosis.

Scientists have discovered that having two or more specific autoantibodies — antibodies that are directed toward your own body — means that you have an almost 100 percent chance of developing T1D in your lifetime. JDRF-funded studies have shown that screening for these autoantibodies, followed by close monitoring, can help significantly decrease the risk of DKA. It also opens the opportunity to participate in clinical trials to potentially

delay or prevent this disease from occurring at all.

Delaying T1D

For many years, programs have helped screen and monitor T1D family members and helped them enroll in clinical trials, which is still a great way to get screened if you have a family history of the disease. However, such programs don't capture the 93 percent of people who do not have a family history of T1D. Without having access to T1D risk screening and knowledge of their risk

status, these people won't have the time to prepare for a T1D diagnosis and prevent the risk of dangerous DKA events or enroll in a potentially life-changing clinical trial.

JDRF launched T1Detect to equip the public with knowledge about the benefits of screening, provide a new avenue to get screened, and offer personal support to those determined to be at risk.

How you can help

If you or someone you know doesn't have T1D and hasn't

been screened, then visit jdrf.org/t1detect to order an in-home test kit. The testing lab will provide the autoantibody results in a few weeks, as well as explanations of what the results mean and important next steps if the results are positive. If you want to share your results with JDRF, you will receive personal support, additional education, and resources to help you navigate your next steps. ▣

Stephanie Loomer

What to Expect When Receiving the Results of Your Clinical Trial



For the majority of clinical trials conducted each year, study volunteers don't receive their results or don't know how to access them.

Nearly all study volunteers want to receive the results of their clinical trials. Regardless of the outcome, participants want any information available that could help them make critical health decisions, and they want to know that their involvement helped others living with disease and illness. In fact, receiving study results is one of the top reasons patients choose to participate, ranked even above the ability to access free medical care.

Pharmaceutical companies and government agencies sponsoring clinical trials are obligated to share the clinical trial results. Most patients first

learn about the results of their clinical trial only after a general announcement has been published in the newspaper or broadcasted in the news. For many study volunteers, the end-of-study experience often leaves them feeling dissatisfied and unappreciated.

Ways to access results

Some clinical trial results are posted on the websites of pharmaceutical companies. Also, federal law requires that clinical trial results are routinely posted on a government website called ClinicalTrials.gov within a year of study completion even if the drug or medical device being tested hasn't been approved. These results, however, are not usually shared with study participants.

Most people find the government website very difficult to navigate. For those able to

locate their specific clinical trial, the results are presented in highly technical language, which makes it hard for not only patients, but also physicians and other healthcare providers to understand.

There is good news, however. A growing number of pharmaceutical and biotechnology companies sponsoring clinical trials want to deliver results in non-technical, plain-language summaries to their study volunteers. At the moment, research sponsors are mainly focused on providing general clinical trial results, but some companies are piloting initiatives to share more detailed, personalized findings with their study volunteers. In the future, study volunteers could potentially attach their own data to their electronic health and medical records, allowing them to

share the results with whom-ever is providing treatment.

What to ask your doctor

If you, a family member, or friend is considering a clinical trial, be sure to ask if the results will be shared. Carefully think about whether you want to participate in a clinical trial if there is no guarantee that the results will be provided to you. If a plain-language summary of the results will be provided, you should ask what options you have for receiving that information. Most study volunteers prefer to receive a printed report, but a growing number of study volunteers are choosing to receive a digital version of the results.

If you have recently participated in a clinical trial, ask your doctor or nurse – or the study staff – to help navigate

the clinical trials website or the pharmaceutical company's website to locate information about your clinical trial. Your nurse and doctor also can be helpful in translating medical jargon into easy-to-understand language.

Study volunteers want to know the results of their participation in clinical trials and that their participation mattered. As partners in the clinical trials process, study participants should expect to receive — and those sponsoring or conducting the research are obligated to provide — plain-language result summaries. ■

Ken Getz, Founder and Chairman, CISCRP



TO THE MILLIONS OF PEOPLE WHO VOLUNTEER FOR CLINICAL TRIALS EACH YEAR.

Clinical research participants make our lives better. They help advance knowledge about disease and improve medicine for generations to come. To learn more about clinical research and to show your appreciation, **visit [CISCRP.org](https://www.ciscrp.org)**.

A sincere thank you to all the medical heroes from the following organizations:

