

Clinical Trials

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The Extraordinary Gift of Clinical Trial Participation

Every year, millions of people choose to participate in clinical research and become partners in the process of developing new medical interventions. We call these brave individuals “medical heroes” in the ongoing battle to understand, fight, and cure disease.



Ken Getz
Founder and
Chairman, CISCRP

Medical heroes can be found everywhere. They are mothers and fathers, siblings, children, friends, colleagues, and everyday people who have chosen to give the extraordinary gift of participation in clinical research. Their decision to participate is an altruistic gift that always carries risk, usually offers no direct personal benefit, yet contributes profoundly to collective knowledge about the nature of disease, its progression, and how to better treat it. Ultimately,

future generations are the direct recipients of this gift.

Most people know very little about clinical trials until they face 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 health-care providers must gather information quickly to make decisions about whether to participate. This rush to navigate the unfamiliar terrain of clinical trials invariably feels overwhelming and confusing.

Appreciating medical heroes

In 2004, the Center for Information and Study on Clinical Research Participation (CISCRP) was founded to provide outreach and education to those individuals and their support network considering participation in clinical trials. Based in the Boston area, this nonprofit organization focuses its energy and resources on raising general awareness, on educating patients and the public, and on 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, and to recognize and appreciate medical heroes.

This special supplement also plays an important part in raising awareness and literacy. It is a reference resource offering an introduction to clinical trials and thanking the millions of people and the clinical research professional community who, together,

help advance medical knowledge.

At the present time, nearly 4,000 experimental drugs and therapies are in active clinical trials, and that number continues to grow as improvements are made in detecting disease, in discovering new medical innovations, and in understanding and addressing the root cause of acute and chronic illnesses. At the very heart of all this promising clinical trial activity are medical heroes to whom we owe our deepest appreciation for their profound gift of participation. ▣

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Biogen's Community Advisory Board Helps Biogen Promote Diversity in Clinical Research

Fifteen years ago, at the age of 42, Israel Robledo was diagnosed with Parkinson's disease. He spent months coming to terms with his diagnosis and realized being a victim didn't suit him. Robledo, who is Hispanic, is one of 18 members from underrepresented communities offering their experience to biotechnology company Biogen.

Community feedback

The Community Advisory

Board (CAB) was established to serve as a bridge between Biogen and communities that have a lack of education, awareness and access to clinical trials.

"Pharmaceutical companies don't have the best reputation," Robledo observes. "But Biogen is building trust. They realize people of different races and ethnicities react differently to medical issues and to clinical trials."

The Board was set up in partnership with the Center for Information and Study

on Clinical Research Participation (CISCRP), a non-profit dedicated to educating patients and the public on clinical research participation.

"Working alongside a diverse Community Advisory Board allows researchers at Biogen to listen and learn in real time," explains Kate Wilson, Biogen's Head of Health Equity on the Patient Engagement, Equity and Transparency team.

Clear messaging

The CAB has provided hundreds

of points of feedback on sharing information to patients, ranging from trial descriptions to travel logistics, or whether a person needs to reveal their immigration status – that information is not collected in Biogen clinical trials, something that is now addressed in its assets.

According to Robledo, the final products are "pretty darn good. I take pride in saying these materials are something that we came up with. Providing a voice is why I became a patient advocate."

Looking to the future

The CAB and Biogen's diversity, equity and inclusion work is garnering industry attention, winning the 2021 Global Pharma Patient Champion Award. The end goal: develop medicines that are safe and effective for all. □

Biogen



"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.





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It is a privilege

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PHOTOS: MATRIX PHOTOGRAPHY & DESIGN

One Man With Alzheimer's Disease Shares His Clinical Trial Journey



“lots of love, support, and encouragement”

Donald MacIntosh had a 25-year career working as an attorney for the Canadian Department of Justice. Smart and with a great memory, he could argue a case referring to just a few pieces of paper. But nowadays, the 69-year-old forgets how to make coffee and can't remember what he had for lunch.

Shortly after he retired five years ago, MacIntosh, who lives in Toronto, noticed he was having memory problems. He went to his personal doctor, followed by a few specialists. On a cognition test with 10 questions, he was only able to answer two correctly.

After additional tests, doctors diagnosed him with early-onset Alzheimer's disease (AD), a form of dementia that affects memory, thinking,

and behavior. The National Institute on Aging says more than 6 million Americans, most over age 65, may have dementia caused by AD.

Gobsmacked

MacIntosh couldn't believe the diagnosis.

"I was gobsmacked," he says, noting his AD might be inherited. His mother lived with it for 14 years before she died, and his father had a gene linked to the disease as well.

While he still retains long-term memories, his short-term memory fades fast. Nowadays, if he wants to water his plants, he has to turn on a light as a reminder to turn off the hose. Minutes after he starts watching a TV show, he can't recall what he's watching.

That's why he was so excited to participate in a

clinical trial for a drug being tested to slow the progress of the disease.

"It is a privilege," says MacIntosh. "Not everyone is in such a trial because either they don't know about it or they don't meet the requirements."

He started the clinical trial in 2016 but recently had to stop participating after he experienced some side effects, including three instances of temporary brain swelling known as ARIA-E.

He credits his wife, Jasmin, with helping him stay as healthy as possible. The couple have been married for 12 years and he's a stepfather to her three children.

"He is so passionate about getting better. He is very disciplined. In fact, he's more disciplined now than he's ever been," Jasmin says. "He gets up, works out, and reads.

He gets involved in discussions with friends. He's very positive about the whole thing, which is wonderful."

Prior to the pandemic, the couple traveled a lot, including cruising a few times a year and going to the theater. MacIntosh still enjoys gardening, socializing with friends, and reading books. He exercises daily, eats healthy, and is focused on maximizing his brain health and cognition.

Jasmin MacIntosh encourages other caregivers to show, "lots of love, support, and encouragement," to their loved ones with AD.

Advocate

Donald MacIntosh does AD awareness outreach with the Center for Information and Study on Clinical Research Participation (CISCRP), a nonprofit dedicated to educating the public, patients, and

medical communities about clinical research.

"People who are afflicted with Alzheimer's and their loved ones are desperately waiting for a drug to come along that not only is efficacious from a safety point of view, but that also has an effectiveness in terms of slowing down the progression of disease," MacIntosh says.

MacIntosh, who remains optimistic, is looking forward to potentially participating in other clinical trials in the future. He encourages other patients to participate, too, explaining there are many benefits including regular exams, free medication, and MRIs.

He has no regrets about participating in a clinical trial. "Even if it doesn't benefit me personally, it will benefit other people in the future." □

Kristen Castillo

Addressing Barriers to Clinical Trial Enrollment

For millions of Americans diagnosed with cancer this year, their best course of treatment might be through a clinical trial.

Clinical trials offer patients with difficult-to-treat forms of cancer a chance to receive the most up-to-date and promising care available with the prospects of improved health outcomes and the benefit of advancing medical research. Most patients express a willingness to participate in clinical research, yet only a small fraction ultimately end up enrolling in a trial due to barriers that make participation difficult or even impossible. Consequently, approximately 20% of cancer clinical trials fail due to insufficient patient enrollment.

Barriers to treatment

One of the most common barriers to trial participation is location. Most cancer trials are concentrated at large academic

centers that have the resources to dedicate to research, yet most cancer patients receive their care at small, local oncology practices. According to a 2018 American Cancer Society Cancer Action Network (ACS CAN) report, Barriers to Patient Enrollment in Therapeutic Clinical Trials for Cancer, only about 1 in 4 patients has access to clinical trials where they are being treated. Yet, if asked to enroll in an available trial, more than half of eligible patients typically agree to do so.

Another barrier is cost. While private health insurance as well as Medicaid and Medicare are required to cover the routine medical costs of trial participation, there is no such coverage for other non-medical out-of-pocket expenses patients may incur.

Trial participants are often required to see their doctors more frequently, which can mean more money spent on things like gas, parking, food, and lodging. Those costs add up, especially for low-income patients. Research has shown financial burdens can lead to a nearly 30% lower trial participation rate among individuals with annual family income of less than \$50,000.

Cancer care inequity

Unfortunately, these barriers and others often contribute to long-standing inequities in cancer clinical trials. Despite having an increased burden of disease, racial and ethnic minority groups, older adults, rural residents, and those with lower socioeconomic status are consistently underrepresented in cancer clinical trials.

This underrepresentation hampers research and, without deliberate efforts to rectify these disparities, research may miss why cancer outcomes are often worse for patients with limited access to care, lower incomes, and other factors.

No one should be disadvantaged in their fight against cancer because of how much money they make, the color of their skin, their sexual orientation, their gender identity, their disability status, or where they live.

ACS CAN has prioritized health equity to ensure that cancer patients are provided with equitable care based on social determinants of health. This is why ACS CAN is working hard to remove these barriers and ensure every patient has equitable access to clinical trials.

Reducing disparities

In 2018, ACS CAN began analyzing common barriers to patient enrollment and provided stakeholders in the research ecosystem with over 20 recommendations that should be taken to make trial enrollment easier for patients. Earlier this year, ACS CAN issued another report targeted specifically at reducing disparities in clinical trials.

Right now, ACS CAN is working to help pass the bipartisan DIVERSE Trials Act through both chambers of Congress. The legislation would help address health equity and disparities by allowing clinical trial sponsors to reimburse patients for non-medical costs associated with their trial participation — such as travel, parking, food, or lodging — and would allow trial sponsors to provide patients with the technology necessary to facilitate remote participation in clinical trials.

The goal of cancer research is to generate new knowledge that can be used to improve survival rates and quality of life for all patients with cancer. But to achieve that goal, it's crucial that clinical trials reflect the broad diversity of cancer patients they're hoping to treat. ACS CAN is dedicated to working with patients, survivors, and their loved ones to ensure that happens and to make cancer clinical trials accessible and available to all interested patients. Together, we can improve access and address healthcare disparities for a world with less cancer. □

Lisa A. Lacasse, M.B.A.,
President, American
Cancer Society Cancer
Action Network (ACS CAN)

The Importance of Telehealth for Rare Diseases

Healthcare must reflect all of the opportunities of telehealth, but especially so for those suffering from rare diseases.

Before the pandemic, telehealth made up less than 0.01% of healthcare visits across the United States. By mid-April of 2020, that number had skyrocketed to 69%. While the concept is not new, patients could not always access it. Then, as

a result of patient advocacy efforts, the COVID-19 public health emergency declaration expanded access to telehealth. This was welcome news for patients, especially those living with rare diseases.

The importance of telehealth

Why is telehealth important for people with rare diseases? For the past year, the team at the National Organization for Rare Disorders (NORD) has

been working to help the rare disease community safely navigate the pandemic. Patients and caregivers have joined us to advocate for expanded access to telehealth, and hundreds have told us about its positive effects. These include helping them feel safer, eliminating days of travel to and from doctor visits, and moving forward with clinical trials that would have otherwise been delayed.

In the case of many rare diseases, there are only a handful of experts nationwide, or even worldwide, with expertise in certain conditions. In the absence of telehealth, patients travel long distances to access their treating provider, often experiencing long waits for appointments. Such travel can be costly, often results in missed work or school, and presents logistical challenges that can be overwhelming or insurmountable when there

is severe burden of illness. Not least of all, travel can pose health risks because many patients with rare diseases are immune-compromised, putting them at greater risk for complications from COVID-19 and other illnesses.

Participation in clinical research is another important area to examine when looking at the role of telehealth. Clinical research is needed for rare diseases, as approximately 90% of the 7,000 rare diseases still do not yet have an FDA-approved treatment. Clinical trials are essential to this process, yet many patients struggle to participate when the clinical trials take place far from home.

Knowing about the uphill challenges that exist, it is easy to understand how COVID-19 has had a significant impact for more than 25 million Americans living with rare diseases. During the pandemic, nearly

8 in 10 rare disease patients experienced canceled medical appointments.

A ray of hope

Despite disruptions to care, a ray of hope emerged with the rise of telehealth: 83% of rare disease patients were offered a telehealth visit by their provider, 92% of those who had a telehealth visit described it as a positive experience, and 70% would like the option for future medical appointments. These numbers show that the demand for telehealth among rare disease patients is strong. With continued information sharing and collaboration among experts, scientists, healthcare workers, and advocates, together we will come out stronger. ▣

**Lisa P. Sarfaty, M.P.H.,
Director of Strategic Planning,
National Organization for
Rare Disorders (NORD)**

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Finally, Clinical Trials that Work for You

Participation in clinical trials has never been easier. Through new devices and technologies and scheduled visits that are closer to home, today patients can participate in ways that are much more convenient and timely. To learn about clinical trials and the important role they play in advancing medical treatments for you, your loved ones, and people around the world, visit **CISCRP.org**.

A sincere thank you to all the medical heroes from the sponsoring organizations.

