

Clinical Trials

DECEMBER 2022 | [FUTUREOFPERSONALHEALTH.COM](https://futureofpersonalhealth.com)



Denise and Bernard Coley

The story of a couple advocating for Parkinson's disease and clinical trial awareness among people of color

02 | CISCRP founder Ken Getz on the everyday heroes at the heart of medical innovation

03 | How Biogen is advancing health equity for improved outcomes across all communities

Clinical Trial Participants' Selfless Gift to Medicine

Each year, millions of people make the courageous decision to participate in clinical research and become partners in the process of developing new medical treatments. We call these brave individuals “medical heroes” because they have given the extraordinary gift of their participation in the ongoing battle to understand, fight, and cure disease.



Ken Getz
Founder and
Chairman, CISCRP



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, to recognize and appreciate medical heroes, and to engage them as partners in the clinical research process.

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 causes of acute and chronic illnesses. At the very heart of all this promising activity are medical heroes to whom we owe our deepest appreciation for their profound gift of participation. ▣

Medical heroes can be found everywhere. They are parents, grandparents, siblings, children, friends, colleagues, and ordinary people who have chosen to give the extraordinary gift of participation in clinical research. Their decision to participate is a selfless act, an altruistic gift; there are always risks but no guarantee

that an investigational treatment will work. Still, medical heroes help us as a society gain valuable knowledge about the nature of disease, its progression, and how — and how not — to treat it. Future generations are ultimately the direct recipients of this gift.

Most people — particularly those in underserved communities — are not aware of, and may not have easy access to,

clinical research. Most stumble upon clinical trials when faced with the sudden and often unexpected prospect of a serious and debilitating illness for which no medication is available or adequate. Typically, patients, their families, friends, and their health-care providers must gather information quickly to make decisions about whether and where to participate. This rush

to navigate the unfamiliar terrain of clinical research can be overwhelming and confusing.

Raising awareness

In 2004, the Center for Information and Study on Clinical Research Participation (CISCRP) was founded to provide outreach and education to those individuals considering participation in clinical trials. This special nonprofit

📷 @MEDIAPLANETUSA 📞 @FUTUREOFPERSONALHEALTH INQUIRIES: US.EDITORIAL@MEDIAPLANET.COM AND US.ADVVERTISE@MEDIAPLANET.COM PLEASE RECYCLE

Publisher **Jessica Berman** Managing Director **Julia Colavecchia** Lead Designer **Kayla Mendez** Lead Editor **Dustin Brennan** Copy Editor **Taylor Rice** Director of Content and Production **Joelle Hernandez** Cover Photo **Denise and Bernard Coley** All photos are credited to Getty Images unless otherwise specified. **This section was created by Mediaplanet and did not involve USA Today.**

Improving Health Outcomes Through Equity and Access

Better access to healthcare equals better health outcomes. Oftentimes, health outcomes depend on factors beyond the control of patients and their doctors. Disparities across age, gender, race, ethnicity, and socioeconomic level are some examples. Biogen's approach toward health equity involves researching

and understanding these issues as well as their compounding factors, such as, inadequate representation in clinical trials and limitations to accessing care. Overall, the goal is clear: improve health outcomes for Black, African American, Hispanic, Latino, and other underserved communities in Biogen's main disease areas.

Issues of culture aware-

ness and mistrust remain prevalent alongside a host of other considerations prior to enrollment in a clinical trial. To address these issues, Biogen uses a multi-channeled health equity strategy which includes incorporating diverse community perspectives and insights into our drug development and engaging with communities by partnering with organiza-

tions to educate, build awareness, establish trust, and drive health equity.

When recruiting for clinical trials, Biogen teams are building patient engagement strategies including setting race and ethnicity recruitment targets for their trials that reflect the patient populations they intend to treat. These targets are supported by robust DE&I and patient-focused drug development strategies. The results are clear with 2021 having 100% of studies in the U.S. including a plan to recruit participants from underrepresented communities to ensure the study population is representative of the intended treatment population.

Biogen has also fostered employee collaboration to increase awareness of health equity needs cross-functionally. In 2021, they introduced

a Health Equity Ideas Cafe Series to deepen organization-wide understanding of Biogen's commitment, including representation in clinical trials and equitable access.

Biogen's approach to health equity is guided by the motivation to help those who have historically been underserved. Concretely, this commitment to health equity looks like: clinical trial diversity, empowering underrepresented groups, engaging employees, and launching new tools to improve accessibility. ▣

Biogen

To learn more, visit,
biogenclinicallink.com



Find out what it means to participate in a clinical trial, and why it matters.

BiogenTrialLink.com



TrialLink

Through Biogen Trial Link, we hope to connect patients, caregivers and healthcare professionals with education and information about our clinical trials.



The Couple That's Empowering Communities of Color to Participate in Parkinson's Disease Clinical Trials

When Denise Coley started shaking one Thanksgiving, her family became concerned. What followed was a Parkinson's disease diagnosis that spurred an empowering journey she's still on today.

Parkinson's disease (PD) is a chronic, progressive movement disorder that occurs when nerve cells in the brain don't make enough dopamine, a chemical that typically helps the body to move easily and with coordination.

Denise Coley, 70 years old and a grandmother of four, was diagnosed in January 2018. She thought her life was over. She had balance issues, trouble walking, stiffness, problems with motor skills, insomnia, and fatigue.

She had a "pity party" for herself but didn't let the disease, which doesn't have a cure, keep her down for long.

Instead, after a long career in supplier diversity consulting and community outreach, she decided to commit to providing education and support to others with PD.

"I just had to take everything that I had from the past — my education, my resources, my experience giving back — and become an advocate to bring awareness to this disease," Coley said.

Cultural awareness

"Denise got the diagnosis, but the family got Parkinson's disease," explained Denise's husband and care partner, Bernard. "Parkinson's affects not just the patient, but all those around the patient, and especially the immediate family."

Denise has resources to manage her disease, as well as the support of her family, but she knows not everyone

with PD is as fortunate. She and Bernard are PD research advocates, especially for Black PD patients and other people of color. They took courses from a learning institute and got empowered as PD patient, caregiver, and now, advocates. They know there are disparities in health that people of color experience, including lack of access, late diagnosis, and lack of cultural awareness in service providers.



“

We are one diverse patient away from solutions to various medical conditions that are out there in the world.

-Bernard

We're putting a pebble in the water, and all those concentric circles are getting **more and more people involved** and educated.

-Denise



The Parkinson's and Movement Disorder Alliance (PMD Alliance) says Black patients have a higher risk of death from PD compared to white patients. A delayed diagnosis is a significant cause of this, with patients often being further along in disease progression. Further, PMD Alliance says more clinical trials need to report their participants' racial composition, since current data shows that less than 2% are Black.

That's why the Coleys, who have been married for 46 years, spent two years assisting the compiling of, "The PD Movers, We Keep Moving: Living and Thriving with Parkinson's Disease in our Black and African American Communities," a culturally sensitive e-book for outreach to the Black community. They say the community needs to get engaged and increase awareness about PD, and stories in the e-book

highlight the challenges and opportunities someone with the condition faces in a culturally sensitive way.

Clinical research

Denise, who's participated in many clinical trials, wants to live her best life. For her, it means being able to engage with her grandchildren. She does Rock Steady Boxing and tai chi, which help improve her balance and motor symptoms.

The couple wants clinical trials to recruit more people of diverse backgrounds, and to get people of diverse backgrounds to help design and review the clinical studies as well.

"We are one diverse patient away

from solutions to various medical conditions that are out there in the world," said Bernard.

Next, the Coleys are doing a Black learning initiative with community outreach and engagement. They are sharing stories of people with Parkinson's disease to help engage the community. They say without engaging and addressing culture, it will be difficult to recruit people from the community to participate in clinical trials.

Their work is having an impact: "We're putting a pebble in the water, and all those concentric circles are getting more and more people involved and educated," says Denise. ▣

Kristen Castillo

Why Participation in Clinical Trials Is a Must for Hispanics



According to UnidosUS, the largest national Hispanic civil rights and advocacy organization in the United States, less than 1% of Latinos participate in NIH-funded health research.

Without clinical trials, “we’ll never push forward,” said Gigi Lozano, Ph.D., a professor and chair of the department of genetics at The University of Texas MD Anderson Cancer Center.

Dr. Lozano spends every day in a science lab conducting tumor studies on mice. She’s confident these studies and other medical research will lead to breakthroughs in cancer.

The value in diversity

Clinical trials need ethnically diverse participants so scientists and doctors can develop a greater understanding of how diseases like cancer impact different people of different backgrounds.

“It’s critical people of all

backgrounds participate in these trials because what works for one won’t work for another,” said Dr. Lozano, a longstanding member of the Stand Up to Cancer Scientific Advisory Committee, helping guide the non-profit’s science portfolio and reviewing its research grants.

The impact of genetics

Dr. Lozano knows genetics play a significant role in whether or not cancer cells develop.

“Culture and environment are two big factors that impact how tumors develop and how they grow,” she said, noting some families have an inherited predisposition to a particular disease.

“In the Mexican American population, they have some genetic predisposition ... there’s a propensity for diabetes and also a propensity for liver cancer, and we don’t understand that,” she said.

Hispanic participation in clinical trials can help researchers figure out how to

track, treat, and ultimately prevent these illnesses.

“[If] we can identify the drivers of the disease,” Dr. Lozano said, “then we can understand [how] to undermine their activities [in order] to kill the tumor cell.”

She says many clinical trials are now based on understanding the genetics of a tumor, picking drugs that fit those genetics, and then seeing what changes happen.

Helping Hispanics

Lack of awareness and hesitation to get involved may be barriers to Latino participation in clinical trials. Language can play a role, too, since most clinical trials are in English.

Still, Dr. Lozano encourages Hispanics to participate in clinical trials for themselves and for the next generation.

“It’s going to help your people. It’s going to help others in your situation,” she said. “It might be your neighbor or a child in your community.” □

Kristen Castillo

Cooking up Fresh Treatments for Food Allergy Patients

—
We are in the midst of a food allergy epidemic.



In the United States, an estimated 32 million have a serious, potentially life-threatening food allergy. The number of emergency claims for treating anaphylaxis to food increased by 377% from 2007 to 2016.

There are no approved treatments for food allergy. Allergists advise patients to avoid problem foods and

always carry epinephrine to treat dangerous symptoms. However, according to a recent survey of food allergy patients, more than half reported mental health concerns related to anxiety because of this.

The good news is that hope is on the horizon. Prospects for food allergy treatment are at various stages of development.

Allergen immunotherapies

Many allergy treatments involve giving patients the food proteins they're allergic to, starting with tiny amounts, and raising the dose over time to increase tolerance. For some, immunotherapy successfully retrains their immune system — they can tolerate the food they were allergic to even after stopping treatment. Others can still tolerate allergens as long as they eat the food each day after completing oral immunotherapy. Some patients remain sensitive to their allergen and some leave treatment due to adverse reactions including hives, swelling, and vomiting.

Methods for food allergen immunotherapies can include eating the problem food, placing dissolved food protein under the tongue, and absorbing food protein from a patch on the skin. Nasal spray food protein vaccines are being studied in mice. Researchers have also safety tested a vaccine containing peanut DNA in adults. Two peanut protein immunotherapies have completed clinical trials and another is

being reviewed by the U.S. Food and Drug Administration for approval.

Other developments

Researchers have made remarkable progress recently in developing anti-allergy drugs created from immune proteins called antibodies. These biologic drugs specifically block the chain of events that cause allergy symptoms. Some are already approved to treat other allergic diseases like asthma and eczema, and they are now being tested to treat food allergies, both as standalone treatments and in combination with food-allergen immunotherapies.

This is a pivotal moment in food allergy research. We have never been closer to offering effective treatments, and the need for those treatments has never been greater. Investing in innovative therapies, diagnostics, and prevention will pay dividends in protecting public health. □

Thomas Casale, M.D., Chief Medical Advisor for Operations, Food Allergy Research & Education (FARE)

LILLY FOR BETTER

LIVES

Our work extends beyond the medicines we create. Together, we're working to improve health and access to life-saving medicines in our local communities and around the globe.

Through partnerships and our signature volunteer programs, we aim to identify and promote successful solutions to health issues that can be scaled and replicated to make life better for people here at home and around the world.

Learn more about our commitment to local communities and people everywhere at [lilly.com](https://www.lilly.com).

Lilly



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.

