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CLINICAL TRIALS

Shauna Whisenton

Follow one woman's journey from patient to advocate

Here's why female-focused trials for HIV are so important

For patients in clinical trials, caregivers are more important than you think

Clinical Trial Participants Are Changing Lives

Ken Getz, Founder, CISCRP

Study volunteers in clinical trials are essential to advances in medicine yet their own medical condition may not benefit by their participation.

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.

Participation in a clinical trial is a brave and selfless act because it always carries some risk. The trial may bring some hope for a treatment and even a cure; but it is unlikely to personally benefit a participant. Through their participation, medical heroes contribute valuable knowledge about the nature of a disease, its progression, and how and how not to treat it. Ultimately, future generations benefit from medical advances gained through clinical trials.

One last hope

For most people, clinical trials are an abstract concept with no personal relevance. They take a hard look at clinical trials for the first time when facing the prospect of a serious and debilitating illness for which no medication is available or adequate.

Patients, their families, friends, and 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 participation is appropriate. This rush to navigate and master the unfamiliar terrain of clinical trials invariably feels overwhelming and confusing.

Learning the ropes

In 2003, 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 educating patients and the public about the clinical trial process and on enhancing study volunteer experiences during and after participation. 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 the medical heroes that inspire us.

Today, 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 of this promising, life-saving and life-altering activity are medical heroes to whom we owe our deepest appreciation for their profound gift of participation. ■

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Expanding Clinical Trial Access for Women Living With HIV

For over 30 years, Merck has been committed to improving the lives of people living with HIV. In those three decades, there have been remarkable advances in therapies to treat and monitor the disease. Today, however, the people who are infected with HIV is changing; there is a silent epidemic of women living with HIV, requiring new ways of understanding the needs of people living with HIV and developing more effective options for treatment and care.

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Globally, there are 18.8 million women and girls living with HIV and approximately 870,000 new cases annually. That means every 80 seconds, a young woman becomes infected. Designing clinical trials for these women presents challenges given their unique barriers. From a cultural, social, and economic perspective, many women with HIV are not aware of or willing to participate in clinical trials. We want to change that.

Connecting through the community

Merck is working with community outreach groups and women living with HIV to understand the burden of the disease and what solutions might help. Partnering with female patient advocates (patients who publicly support or make recommendations for a disease) has helped us to listen and learn about known barriers to clinical trial engagement and to develop a female-focused recruitment strategy for our clinical trials. A community advisory board also helps generate solutions that address patients' questions and helps them overcome challenges to participating in a clinical trial such as transportation or even child care.

Kathleen Squires, M.D., Merck Scientific Affairs, reiterates the importance of evolving our approach to better meet the needs of women with HIV. "Less than 20 percent of HIV clinical trial participants are women. Women may be at higher risk for complications, and we need to understand these risks and address their concerns and needs if we want to design effective trials and medicines." Bringing meaningful input from women living with HIV into the design of clinical trials helps us partner with patients to make trials more women-friendly. ■

Jan Nissen, BSN, MBA, MS Pop Health, VP Patient Innovation & Engagement, Merck & Co., Inc

How a Clinical Trial Participant Became an Advocate for the Sickle Cell Community

Shauna Whisenton thought she'd live with sickle cell disease for the rest of her life — until one clinical trial changed everything.

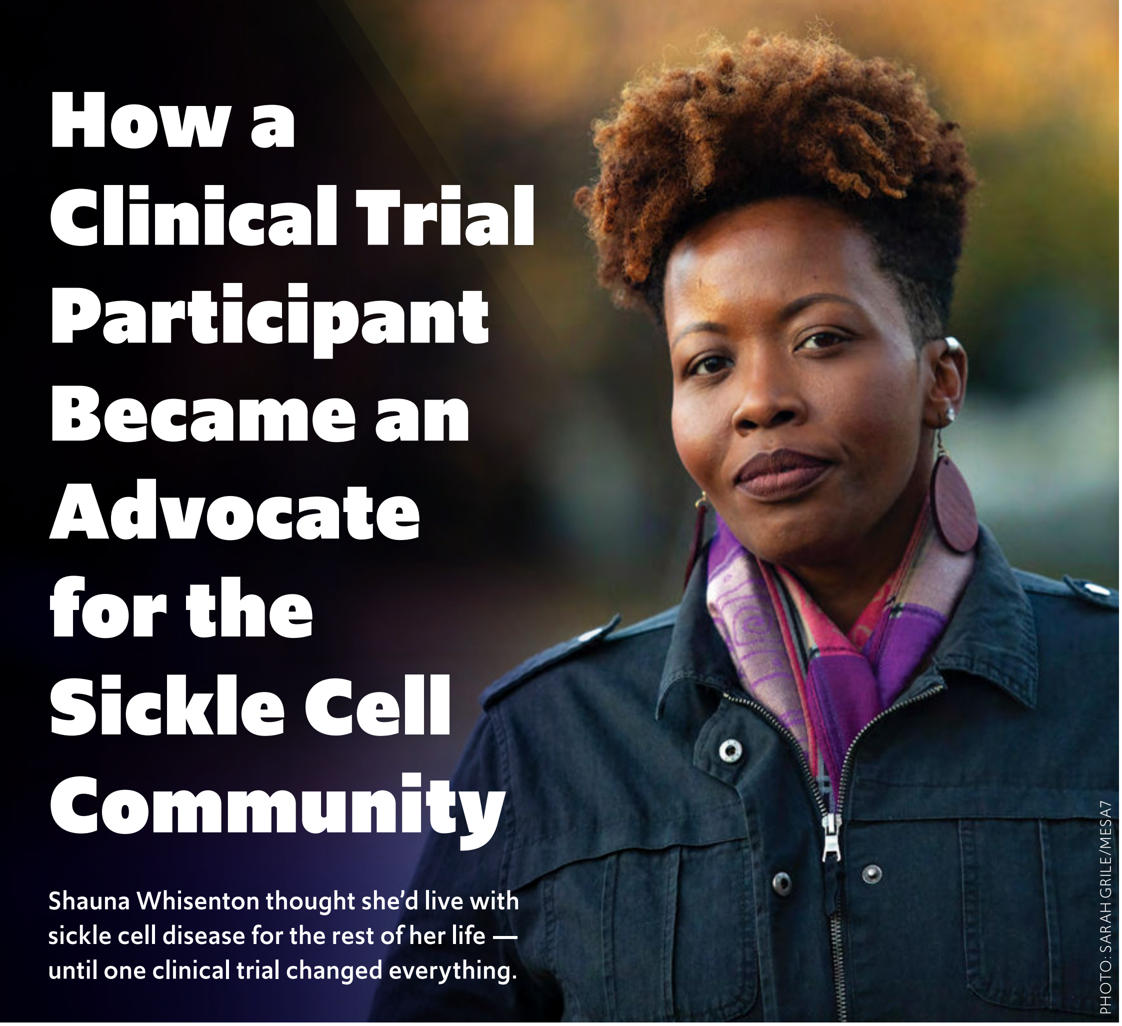

PHOTO: SARAH GRILE/MESA7

Shauna Whisenton was once an individual living with sickle cell disease (SCD). Now she's an advocate for better therapies, a cure, and better understanding of SCD.

Whisenton, now 41, was born with SCD, a painful, inherited disorder where red blood cells are misshaped, restricting blood flow and oxygen to parts of the body.

"It was all going pretty well until I had my third son," she says. "Then my health started to take a turn for the worse."

While nursing, she was admitted to the hospital every few weeks and, despite best efforts, was not replenishing enough fluids for her body to function properly and had major organ complications.

Her doctor asked her to consider a bone marrow transplant clinical trial to cure SCD.

Whisenton didn't believe she could be cured and some members of her family were unsure if she should undergo the treatment. For many in the minority community, there is a fear that medical testing may exploit patients instead of helping them. However, clinical trial oversights ensure safety during participation.

After consulting an SCD patient advocate, she realized, "Although a cure is not guaranteed, this could be an amazing opportunity. If that is not possible for me, researchers could learn something from my participation to save others."

Finding a donor

The best chance for a donor match would be a family member. Whisenton lost her parents when she was a child and her sister wasn't a match; but her 9-year-old son, Dorian, was a 50-percent match.

A successful transplant meant a better life for Whisenton and her family.

"I felt like my children had suffered enough watching my pain," she says.

Whisenton's son had marrow extracted from his pelvis bone. It was a one-day procedure for him but the start of a two-year ordeal for his mother.

Journey

Whisenton's journey was tough. She was hospitalized, received anti-rejection medications, and had to undergo chemotherapy. She persevered with support from family and her medical team. For Whisenton, treatment beyond the transplant was an important part of procedure preparation and recovery. This included coordinated care to provide relief from the symptoms of her disease and the transplant, including pain and detoxing from opiates, but also the physical and mental stress from the procedure.

"It's important to equip someone who's received a curative therapy with tools to rebuild their lives during and after recovery," she says.

Within nine months of receiving the bone marrow transplant, Whisenton was SCD-free and now only carries the trait.

Whisenton calls the date of her transplant her birthday.

Patient advocate

Whisenton has made it her life's work to help those living with SCD. She's the manager of sickle cell disease community engagement for the ASH Research Collaborative (ASH RC) Sickle Cell Disease Clinical Trials Network (CTN), established by the American Society of Hematology, the world's largest professional society concerned with the causes and treatments of blood disorders.

Whisenton is carrying out the mission of the ASH RC CTN to improve the lives of individuals with SCD by expediting the development of new therapies through innovative clinical trial research. Whisenton ensures that the voice of the patient is heard at all stages of these clinical trials.

"SCD warriors, don't lose hope. There are many treatments in the pipeline to help those living with this disease have a better quality of life. Our hope is that advances in research will bring more effective treatments to individuals living with SCD." ■

Kristen Castillo

What Does a Caregiver Need?

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Dealing with significant health challenges requires expert medical care and the support of committed caregivers who always have the needs of the patient in mind. But what do caregivers need to do this effectively? When Don Selmon's wife, Carla, was diagnosed with cancer, he found his sudden role as her caregiver overwhelming. "There is so much information to process and keep track of," he says. "There is simply too much data to try and remember not to use some sort of system. I personally created Excel spreadsheets so I could keep track of drugs she was taking for side effects, daily vitals, upcoming scans and appointments, question sets when meeting with our trial doc, etc."

Selmon's experience as his wife's caregiver quickly showed him how vital that role is. "We can't sit still with an enemy like cancer," he says, noting that as a caregiver his roles included "cheerleader, confidant, shoulder to vent on — always doing my best to have her back in meetings and in treatment."

Another crucial role caregivers play is often overlooked: helping patients discover clinical trials that can offer hope, relief, and, possibly, the greatest gift of all: more time.

Finding clinical trials

"Caregivers play a critical role in helping patients process the information that they are hearing from their treatment team and help them weigh the options," says Sharon Hanlon, head of clinical trial engagement and enrollment at Bristol-Myers Squibb (BMS). "They may play a role in the decision to participate in a clinical trial, doing some homework on behalf of the patient to help with their decision."

Caregivers often start with a simple online search to find out about clinical trials. Web resources like clinicaltrials.gov can be easy to find, but trying to use because the trial descriptions can be difficult to read, and often assume a medical background that many caregivers lack. To help caregivers more easily access this crucial information, many pharmaceutical companies have created patient-focused websites that make it easier to identify appropriate trials.

"Ours is BMS Study Connect," says Hanlon, "which utilizes patient-friendly language to help simplify the process and help make the journey easier. We also provide informational resources such as patient stories, such as the one here of the experience of a patient and caregiver during their clinical trial."

At Study Connect, patients or their caregivers can use straightforward tools to find potential clinical trials they can participate in. Even though the site is run by BMS, Study Connect searches all possible trials, even those not sponsored by BMS, something similar websites don't offer.

Supporting caregivers

Despite their vital importance, the tremendous — and sometimes exhausting — efforts caregivers contribute is not always visible. "I often say that caregivers are the forgotten member of the patient experience," Hanlon says, noting that they often experience feelings of powerlessness and stress around the experience. Caregivers are just as much in need of emotional and practical support as the patients they're looking out for, and companies like BMS have also set up online resources where caregivers can exchange information and support each other.

"Web communities present an outlet for caregivers," Hanlon says, "providing access to information." For example, BMS participates in the Inspire Community making it available for patients, caregivers, and healthcare professionals. Members of the forum can support each other emotionally, compare notes, and discuss trials they have learned about or are participating in.

Inspire surveyed patient and caregiver members about clinical trial perceptions in late 2018, and found that almost a third — 31 percent — of all respondents had tried to sign up for a clinical trial, and 21 percent agreed with the statement "clinical trial information is too confusing." As a result of this information, now many Inspire communities have sections that are devoted specifically to clinical trial discussions to provide support and further information.

However, different people use Inspire in different ways. For Don Selmon, it was a vital connection to shared experience. "I utilized Inspire to learn more about the reported impacts of various treatments," he says. "It was of great benefit to me as it helped me prepare as a caregiver for what might come from my wife's treatment and how best to help her."

Sometimes that connection is the best help a caregiver can receive. As Hanlon notes, "Sometimes the simplest connection is often the most impactful!" ■

Jeff Somers

What Information Matters Most When Deciding to Participate in a Clinical Trial?

In a recent survey, people from around the world provided their thoughts on what they need to know when deciding whether a clinical trial is right for them.

When facing a serious illness, it's natural for patients and their loved ones and caregivers to seek every potential resource. One of the most promising of those resources is often the most intimidating: the clinical trial. While any decision should begin with a conversation with a trusted doctor, people will have different concerns that go beyond the purely medical. Being able to answer these questions can make the decision to participate much easier. That's why the Center for Information and Study on Clinical Research Participation (CISCRP — www.ciscrp.org) recently asked over 12,450 public citizens and patients from around the world for their thoughts about clinical trials.

Universal concerns

The most common concern people expressed is the most obvious. Eighty-one percent of the respondents said knowing the potential risks and benefits of a trial is "very important." Knowing the purpose of the clinical trial (74 percent) and the types of medical procedures required (71 percent) followed closely. Many people are naturally concerned about how participation in a trial might affect their everyday lives, with 58 percent of respondents noting that potential costs and reimbursements were very important, 57 percent responding they would be concerned about the physical location of the study clinic, and 54 percent considering the duration of the study to be an important factor.

Individual concerns

The journey to clinical trial participation may be paved with uncertainty, but having answers to important questions can help make the decision process a smoother one. The Perceptions and Insights Study helps identify better ways for the public, patients, and clinical research professionals to work together to develop new medical treatments.

Jeff Somers

Understanding the Patient-Centered Approach to Treating Sickle Cell Disease

Sickle cell disease (SCD), the most common inherited blood disorder, affects an estimated 100,000 Americans. It's a painful lifelong disease but clinical trials may help develop new treatments and even find a cure.

SCD, is marked by abnormal hemoglobin protein inside red blood cells, causing those cells to be rigid and C-shaped, like a sickle. These sickle cells can block blood flow to organs and cause severe pain and complications, including organ damage and stroke.

In the United States, it's most common among African American and Hispanic people; however, it can occur in other racial and ethnic groups.

Clinical trials

While there is no cure, currently there are U.S. Food and Drug Administration (FDA)-approved drugs. More than 40 therapeutics are in development to treat or cure SCD. Those new treatments will need to be tested and approved by the FDA for patient use. That means there will be increased need for SCD patients to participate in clinical trials.

"We are entering a new age in SCD research," says Chuck Chesson, Ph.D., the director of the ASH Research Collaborative (ASH RC) SCD Clinical Trials Netwxsork (CTN). "We are all excited to be a part of finding better treatments for those living with sickle cell disease."

In 2018, the American Society of Hematology established ASH RC, which launched the SCD CTN to foster expediting therapies and facilitating clinical trial research innovations.

Patient-centered approach

"We are really focused on building a research community within the sickle cell population," says LaTasha Lee, Ph.D., MPH, senior manager of partnership engagement for the SCD CTN.

Patients and the community don't always realize all medicines need clinical trials to test efficacy and safety, so the CTN is focused on educating the SCD community about clinical trials. They've hosted many in-person community engagement workshops across the country with members of the sickle cell community.

This patient-centered approach is helping patients and their families understand the clinical trials process and ask questions comfortably. The ASH RC encourages the advancement of research that meets the needs of the SCD Community.

"If not you, then who?" a SCD Community Workshop attendee shared. "If no one stands up to participate in clinical trials, we won't have any advancements in the field." ■

Kristen Castillo

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Demystifying the Clinical Trial

Clinical trials depend on their most vital resource: the patients. A new program is working to improve their experience.

Clinical trials benefit humanity as a whole and may have a positive impact on the lives of the people who participate in them. This is especially true when they can establish strong relationships with the investigators and staff — studies demonstrate that better communication between patients and medical professionals results in better care and less stress for both.

A lack of effective communication remains a challenge, however. “I think clinical trials are a mystery to many people,” says Suzann Johnson, associate director of patient experience at Janssen Pharmaceuticals. “We had conversations with our investigators, and I think the investigators are recognizing there may be a need to improve communication with patients.”

Improving communication

Susan Kesler, a nurse with 35 years of experience working as a site coordinator with Dayton Gastroenterology, Inc., agrees. “It’s really all about the patient,” she says. “We want to help you with your conditions. I think more open communication with the patient from the physician is very important.”

The key, Kesler says, is treating each patient as unique. “It’s all about, how can we help you?” she says. “The patient needs to feel safe and secure. We always give them all the information and encourage them to talk to their family. I like to tell my patients, you have to be comfortable with what you’re doing.”

Janssen sees a future where every clinical trial is patient-focused. “Communication is difficult as it is,” says Johnson. “When you add in the variable of someone who’s dealing with a disease, they don’t know what to expect in clinical research. That was the impetus behind developing the HealthCaring Conversations program.”

A patient-focused roadmap

HealthCaring Conversations is focused on ensuring participants in clinical trials feel heard and empowered. “HealthCaring Conversations provides a blueprint to a conversation that really keeps the patient at the center,” says Johnson, “while also acting as a roadmap that speaks to what the patient is interested in. It really personalizes the conversation.”

The program is a 20-minute interactive module clinicians take in their own time, modeling conversations and allowing the clinician to choose responses. “Within that span of 20 minutes,” says Johnson, “we’re bringing forward this model with three main tenets: understand, connect, and empower.”

That empowerment is crucial, she says, because the future depends on the people who volunteer for clinical trials. “The reality is that new treatments and new medicines don’t come onto the market without clinical trial volunteers.”

Kesler agrees. “We want patients to understand they’re contributing to the larger picture. Down the road, this could help your grandchildren.” ■

Jeff Somers

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

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