

A Guide to Advancing Medicine Through Clinical Trial Participation

# Clinical Trials



## Melvin Mann

The cancer survivor shares how a clinical trial gave him a new lease on life

CISCRP Founder and Chair Ken Getz talks about why clinical trial participants are medical heroes

How the CCF is engaging patients and doctors to participate in IBD clinical studies



# Why Clinical Trial Participants Are Medical Heroes



**Ken Getz**

Founder and Chairman,  
CISCRP; Professor, Tufts  
University School of  
Medicine

**We can thank safe and effective COVID-19 vaccines for their essential role in healing the world and putting the global pandemic behind us.**

**T**hese vaccines were developed very quickly. The global community of scientists and research professionals worked closely together, openly shared information about COVID-19, in some cases used vaccine technology that was already in development for similar viruses, and began conducting clinical trials shortly after the pandemic began.

But the ultimate success of COVID-19 vaccines, and

the thousands of drugs and treatments in clinical trials for all diseases, depends entirely on people who participate in them. We call these brave individuals “medical heroes.”

Medical heroes are people who have chosen to give the extraordinary gift of their participation in clinical research to find new treatments and cures. Their decision to be a clinical trial volunteer is a selfless act — because it always carries risk and may not result in any direct personal benefit.

It is true that participation usually brings hope to clinical trial volunteers and their loved ones. But more often than not, it is other patients, now and in the future, who are the direct recipients of the gift of participation. Medical heroes, in partnership with clinical research professionals, contribute profoundly to our collective knowledge about the nature and progression of disease, and how and how not to treat it.

## **Raising awareness**

Even with more media atten-

tion on clinical trials today, the majority of people know very little about what it means to be a study volunteer. Most people only look at clinical trials when facing the sudden and often unexpected prospect of a serious and debilitating illness for which no medication is available or adequate. At that moment, patients, their families, their friends, and their healthcare providers have to gather information quickly to make decisions about whether to participate. For most people, this rush to navigate the unfamiliar landscape of clinical trials feels overwhelming and confusing.

Seventeen years ago, the Center for Information and Study on Clinical Research Participation (CISCRP) was founded to provide outreach and education to all people and their support network considering participation in clinical trials. Based in the Boston area but with global reach, this unique nonprofit organization focuses its energy and resources on raising general awareness, educating patients and the public, helping people find clinical trials, and enhancing study volunteer experiences during and after clinical trial participation.

This special supplement is part of CISCRP’s ongoing effort to educate and inform, and to increase public recognition of the millions of medical heroes giving the gift of participation in clinical trials each year. We hope you find the following pages informative and inspiring. □

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# How Clinical Studies Are Building a Brighter Future for People With Deafness



**We've all seen the viral videos of children born deaf hearing their parent's voice for the first time, and lighting up with glee or breaking into sobs at the foreign sensation of audibility.**

What many of us do not realize is that behind that technology, be it a common hearing aid or a cochlear implant, were ambitious researchers and a brave group of patients willing to give it a shot in a clinical trial.

Today, hundreds of thousands of clinical trials and studies are ongoing, and

they may lead to the next big advancement in restoring lost hearing or improving the quality of life for those individuals living with it.

## **Living proof**

Years ago, Sonia Morreale didn't hesitate to sign up her son Justin, then 8, for a clinical study on how children who grow up with cochlear implants tend to fare in language and comprehension.

"I wanted to know that information," she said, "and I knew that it would help not just my own child, but that [the researchers] would be

giving this information to other parents."

As the results suggest, and as Justin demonstrates, growing up with cochlear implants isn't as limiting as many may suspect. Now 16 and living with two cochlear implants to correct the genetic profound deafness he was born with, Justin has over a 4.0 GPA, is enrolled in AP and honors classes, and is in the process of getting his driver's license.

From the moment she heard Justin cry at the sound of her voice after receiving his first cochlear implant at age

2, Sonia knew the future held big things for her teenage son. "It gave me a lot of hope."

## **Selfless motivation**

Dr. Laurie Eisenberg, professor of research otolaryngology at the Keck School of Medicine of USC, which conducted the study, says the Morreale family's inspiring story is one of many she's seen in the 41 years she has worked in the field.

"Seeing a patient hear for the first time is always an emotional experience," Eisenberg said.

She notes that while some patients may be hesitant to

enroll in trials due to safety concerns or feeling inconvenienced about travel, those who do enroll are carrying out a selfless act.

"Many adults feel like, 'If I can help a child, then maybe it is worth it,'" Eisenberg said. "It's an intrinsic motivation that, 'My experience and involvement in science can help others.'"

Sonia put it simply: "I just think that, as a parent, I don't see any cons — I see only the opportunity for gain." □

**Melinda Carter**



e hoped to live at least eight years and spend some more time with his wife and their then 5-year-old daughter.

Little did he know that he'd go on to run marathons, exceed his doctor's expectations, and watch his little girl grow up to become a doctor. His incredible journey was possible thanks to clinical trials.

### Diagnosis

At the time of his diagnosis, Mann was a 37-year-old Army major. He was stationed in Detroit and had been experiencing chronic back pain for more than six months. He also had night sweats. In December 1994, he had an MRI before Christmas but didn't think anything significant was wrong.

A month later, he got his results. The MRI showed he

# How Clinical Trials Saved This Cancer Patient's Life

When Melvin (Mel) Mann was diagnosed with cancer 26 years ago, his doctors gave him a three-year prognosis; the average for patients with his type of cancer.

had a herniated disc and possibly leukemia. Further testing showed he had chronic myelogenous leukemia, a blood and bone marrow disease where the bone marrow makes too many white blood cells.

"I get this unexpected diagnosis that really puts an end date to my life," he

recalled. "I'm just in shock because that's the first time I ever had to deal with my own mortality."

The doctors told him his best hope was to get a bone marrow transplant. A sibling is often a potential donor but his sister was not a match, so he started looking for a donor on the national donor registry.

He says at the time, the odds of Mann, who's Black, finding a Black donor match was about 1 percent.

He was undeterred. Over the years, Mann signed up thousands of people to the bone marrow donor registry, including holding drives at the Pentagon in Virginia, and in Pennsylvania, Georgia,

and many other places in the United States and around the world. He felt a sense of urgency to register donors to potentially help others.

### Clinical trials

Mann, who took a medical retirement from the military and moved to Atlanta, says looking for a treatment saved



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PHOTO: CECILIA MANN

**Feels good**

Now 64, Mann is a proud patient advocate who does outreach work with many organizations, including the Leukemia and Lymphoma Society, and the Be the Match donor registry.

He's still running and is grateful he got to see his daughter grow up. She's a psychiatry specialist, who graduated from Harvard College and Emory Medical School.

He's honored to have been a part of the clinical trial that's helped so many cancer patients.

"The further I get out, the more I can see people taking Gleevec," said Mann, who's the world's longest living Gleevec patient. "To know that I was part of something like that, the groundbreaking research, feels good." □

**Kristen Castillo**

his life. While he never did get a bone marrow match, during one of his donation drives, he met a businessman who survived cancer and had received treatment at MD Anderson Cancer Center in Houston.

He followed the man's advice and visited MD Anderson. The doctor there told

Mann there was still time to help him. He was 18 months into his three-year prognosis.

The doctor adjusted his medicine and enrolled him in clinical trials. Eight months later, in August 1998, he was the second person at the facility to participate in a clinical trial for a drug called STI571, known generically as Ima-

tinib or by the brand name Gleevec. He was one of only 20 people across three locations to try the medicine.

Mann lost a lot of weight, was frail, and slept a lot. He slowly improved as his doses increased. In June 1999, he was able to run a marathon.

At the time he started the clinical trials, Mann didn't

know how long the medicine would last, let alone that he'd still be taking the same medicine today. These days, his cancer is in remission and he gets routine blood work done every three months.

He advises other patients, especially people of color, to consider all their options, including clinical trials.

## Boehringer Ingelheim Honors CISC RP's Medical Heroes & Encourages Patient Participation from all Backgrounds



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Boehringer Ingelheim is proud to work alongside the unsung heroes of clinical research and medical progress, including our patient participants, investigators and research staff that help lead the way to the identification of new medicines and therapies. We value the gift of patient participation from all backgrounds, especially as health disparities persist and the need exists to optimize diversity to promote balanced representation for all populations.

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# Why Patients and Doctors Need to Get Involved in Clinical Trials

Patients with inflammatory bowel disease (IBD) know there's no cure for their illnesses. Still, there's hope for new treatments, therapies, and an eventual cure.

**T**hose remedies start with clinical trials, or research studies looking into the effectiveness and safety of medical treatments and devices to treat a variety of conditions.

## Need for new treatments

The Crohn's and Colitis Foundation (CCF), a national resource for adults and children with Crohn's disease and ulcerative colitis, is spearheading an effort to get patients and medical providers involved in clinical trials.

"The risk of not participating in a clinical trial is that there will be less information about potential cures and new treatment options for patients in the future," said Courtney Bisbee, the manager of patient education for CCF.

"There currently is no cure for Crohn's disease and ulcerative colitis. The only way that new treatment options that can potentially cure these diseases are going to happen is through clinical trials, where the FDA can review data and approve the new treatments as safe and effective for patients."

## Simplifying the process

Right now, IBD doctors looking to enroll their patients in clinical trials need to search for a trial on [clinicaltrials.gov](http://clinicaltrials.gov). But the site is cumbersome,



some, especially since it's used for all the clinical trials in the United States, not just IBD studies. That's why CCF has secured funding to create its own clinical trials database specifically for patients with IBD. The clinical trials' matching service will take a patient profile, pull data from [clinicaltrials.gov](http://clinicaltrials.gov), and then create a customized list of trials the patient might be eligible for based on their disease type, their location, and their treatment history, among other factors.

"The majority of patients I've talked with have said they've entered a trial because they felt they could individually benefit

from it, in addition to wanting to contribute to IBD research to help other patients like them in the future," said Bisbee, who developed and manages CCF's database "Clinical Trial Community."

In the meantime, CCF has provided patients and providers with the customized IBD Clinical Trial Finder tool to search for local trials in their area

## Awareness

Despite the availability of clinical trials, not all patients and providers are aware of the studies.

"If the patient is unaware of a clinical trial as a potential treatment option and doesn't

understand what their participation in a clinical trial may look like, they are less likely to enroll in a trial, therefore making it difficult for researchers to advance new treatment options," said Bisbee, who encourages gastroenterologists to talk to their patients about clinical trials as one of the many treatment options available to them. "We need patient participation to show if any of these treatments are ultimately safe and effective."

## Barriers

Even if patients know about clinical trials, they don't always sign up. CCF conducted focus groups of IBD patients

in Idaho, Miami, and Connecticut to get an idea of what patients think about clinical trials. The results? The majority didn't know much about them.

Patients were worried about feeling like guinea pigs, and they feared getting a placebo instead of the actual drug. They were concerned their disease would worsen if they took the placebo.

Other worries included wondering if insurance would cover the medication and feeling concerned about paying transportation fees and childcare costs while traveling to the trials. In reality, pharmaceutical and biotech companies often cover the cost of the trials. In some studies, if patients receiving a placebo find their disease getting worse, the patient can receive the drug later.

The CCF's Clinical Trials Community was developed in order to address these patient concerns, and to help increase awareness of trials and educate patients about participation. The program launched in July 2017 with resources for adult patients and professionals. The program expanded in 2018 to include additional adult patient resources, as well as a full build out of pediatric clinical trial resources in collaboration with ImproveCareNow and NASPGHAN. □

**Kristen Castillo**

Laurie was searching for hope. John was seeking new experiences. Alison wanted to help end the pandemic.

The motivation of a clinical trial participant is as unique as the person themselves. By participating in a Pfizer clinical trial, Laurie, John, and Alison each walked away with a sense of satisfaction, and a feeling that they helped advance science.

### Living proof

Six years ago, Laurie was told by her doctor in Alberta, Canada, that she'd exhausted her treatment options for her metastatic breast cancer. So, her daughter started researching clinical trials, and found a Pfizer trial in Portland, Oregon that was a fit. Before the trial began, Laurie was preparing for the worst. "My outlook was pretty grim," she says. Now, six years later, at age 62, Laurie continues to be involved in the trial, and is living her life in a more fulfilling way than she could have imagined. "There is a lot of hope," she says. "I consider myself lucky."

John knew several people who had participated in clinical trials, and he was curious about the experience. He decided to look into a Phase 1 Pfizer clinical trial, which would test the safety of a study drug over a matter of weeks, and joined after going through the screening process. During the trial, he lived in Pfizer's research facility in New Haven, Connecticut, with the other participants. In his downtime, he made friends in the multimedia and relaxation rooms.

John, who is 56, enjoyed his experience so much that

he's since joined 10 other Pfizer clinical trials, as well as trials sponsored by other companies. In the process, he's learned a great deal about health, and takes better care of himself. "I'm more conscious of what I have to do to keep myself healthy and to try to avoid getting some of the illnesses that are brought on by the way you live," he says.

Last year, as the world waited anxiously for development of a Covid-19 vaccine, Alison decided she wanted to help. An online search led her to a Pfizer vaccine clinical trial near her home in the Los Angeles area. "I felt it was

really important we lead with science as we tried to fight this pandemic. And science can't happen without people who are willing to take part in trials," says Alison.

During the trial, Alison, who is 37, received two shots about three weeks apart. In February, she learned that she was among the group of people in the trial who received the placebo. She accepted an option to receive the study vaccine and continue being monitored as a participant in the clinical trial. Today, as she watches the news and hears the vaccination stories, she knows

she played an important role. "Millions of Americans at this point have been vaccinated, and that was because a small number of people said they were willing to do the trial," says Alison.

### Advancing science

For clinical trial participants, the reason is always personal. For many, those reasons evolve even as the trial goes on. In the end, the trial participants interviewed for this story all felt a sense of accomplishment, knowing that they'd helped advance science, while also achieving some of their own goals along the way.

# When Joining a Clinical Trial, Each Participant Is Driven By Their Own 'Why'



PHOTO: COURTESY OF PFIZER

Laurie, Alison and John (from top, clockwise) felt fulfilled by participating in a clinical trial.

When Alison reflects on her experience, she feels thankful that she was able to be a part of research at a critical time. "There have to be people who are excited and interested and willing to get involved for the science to happen," says Alison. □

**Kate Silver**



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