



**Medical Hero in the Spotlight**

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# A Painful Loss and “Unbearable” Images Inspire Healthy Volunteer

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A perfect storm of wrenching emotional events set Kymone Freeman, a 39-year-old poet and playwright from Washington, DC, on a mission to help eliminate AIDS—and to participate as a healthy volunteer in the search for a vaccine.

Ten years ago, when Kymone’s favorite uncle died from AIDS at age 54, Kymone was stricken with grief at losing the man “who was like a father to me.” His uncle’s illness and death were made even more painful and poignant by his family’s reaction of denial.

“They tried to pretend that he just got sick and passed away from anything but AIDS,” says Kymone. “My family would not visit my uncle in his final days in the hospital because they feared they would contract the disease. They wouldn’t even let me visit him.”

Kymone’s awareness of AIDS’ potential devastation grew even stronger in 2004. That year, he went to Kenya with the American Friends Service Committee (AFSC), a Quaker program which sponsored a Youth Leadership trip to Kenya.

“We visited AIDS clinics in Nairobi and the countryside. We went to orphanages that housed children who had lost their parents to AIDS,” says Kymone.

“Seeing people who were dying without comfort and beyond help was unbearable. That opened my eyes to the worldwide AIDS pandemic,” says Kymone.

Kymone also noticed that his home, Washington, DC, had one of the highest rates of new AIDS diagnoses in America.

**Tough decision to become a healthy volunteer**

In 2007, Kymone attended a presentation given by the National Institutes of Health (NIH) explaining an upcoming AIDS vaccine clinical trial.

Besides feeling strongly that AIDS needed to be eliminated, Kymone believed that an AIDS vaccine was the only hope to make a real difference. He distrusts pharmaceutical companies’ efforts to develop a vaccine, feeling that the companies know they become more profitable from treating—rather than preventing—AIDS. “I believed in the vaccine,” says Kymone.

Although Kymone wanted to participate in the trial, his long-term girlfriend was adamantly opposed.

“When I told my girlfriend I was thinking about doing the trial,

it caused a lot of problems,” he said. “We didn’t break up, but it came at a high cost at home.”

The NIH site staff described the treatment’s potential side effects to Kymone. At first he was intimidated by the list of possible harmful effects. Then, says Kymone, the NIH staff took the time to discuss and explain the potential effects and the likelihood of their occurring. Their patience and willingness to spend time in discussions with him overcame Kymone’s initial reservations.

“The only side effect I had during the trial was that I caught a cold the two times the vaccine was introduced. But it was winter, so possibly it was just a common cold I would have gotten anyway,” says Kymone.

Kymone’s participation lasted about nine months. “I went to the site about once a month and would get a shot or give a blood sample to see how my body was responding,” he says. “I couldn’t be tested by actually being exposed to the AIDS virus, but the goal of the trial was to see whether the body would stimulate the antibody response. That’s the great leap of faith.”



Kymone Freeman

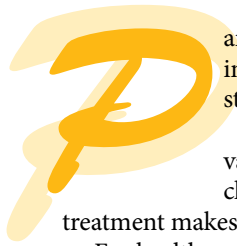
As the founder of the annual National Black L.U. V. (Love Unity Vision) festival, which provides free AIDS screening for attendees, Kymone is no stranger to public attention. However, he did face some backlash when he became one of the participants featured in the NIH/NIAID Vaccine Research Center’s advertising campaign.

“People came up to me and offered condolences because they thought I was HIV positive,” he says. “I said, ‘No, that’s not what the sign says!’ But they saw my face there and made the connection.”

While Kymone is glad that he enrolled in a clinical trial, he’s not currently planning to get involved in another one. Still, he encourages others to consider taking part.

“What I’d say to anyone who is thinking about it is, ‘Educate yourself, educate yourself. Involve your family and friends in the decision.’”

# Should I or Shouldn't I? How to Weigh the Risks



Participating in a clinical trial is an intensely personal decision, and the stakes differ for each person.

For those with a serious, advanced stage disease, even a slight chance of getting a more effective treatment makes the decision easy.

For healthy volunteers or people with less critical conditions, potential side effects and other factors need to be balanced against the desire to take part. Most people who consider trials participation do some soul-searching as they weigh the pros and cons.

There are several reasons that people may choose to participate:

#### To gain access to new treatments

There's the chance that an experimental treatment or a new and better treatment will help your condition improve. Many clinical trials have introduced treatments that were more effective than those that were currently available.

#### To advance science and help others who have the illness

Helping to develop new treatments that could aid thousands and advance science is a powerful motivation. Many people with this goal are willing to assume some risk because they feel they are contributing toward making the world a better place.

#### To earn extra money

For some people, the compensation offered is an attractive incentive to participate.

#### To receive free medical care

The experimental treatment is typically free to the participant. In addition, while volunteers are taking part in the trial, site staff usually monitors their vital signs and pays attention to other symptoms and health factors.

But potential volunteers also have to weigh the risks and balance them against the potential benefits. Some of those negatives include: **You might get a placebo (a pill or treatment that has no effect) instead of the test drug**

Some tests include a control group that gets a placebo—at least for part of the test period—and if so, your disease is not treated during that clinical time frame.

#### You may be exposed to harmful side effects

Although many volunteers experience no side effects or only minor effects, there are po-



tential risks with an experimental treatment. This factor may weigh especially heavily on healthy volunteers.

#### A standard treatment is already available

If your current treatment is helping you even slightly, you may feel that's better than trying a new treatment that might not work at all. You'll also probably have to stop taking your current treatment, which could lead to a relapse.

#### Taking part in a trial may be inconvenient

You may have to get frequent injections or have blood drawn regularly; undergo exams or possibly quit smoking, drinking or other activities that are routine for you.

Visiting the test site, monitoring your physical responses, and keeping a journal, if required, may be burdensome to you.

#### You may incur unexpected costs

Although in most clinical trials the study drug and the direct cost of care are paid for by the study sponsor, there may other costs associated with the visits, including, but not limited to lodging and transportation costs to visit the test site.

“ I know what I went through with chemotherapy treatment. If I can in any way help someone else not go through that, it can't be anything but good. The trial I'm in is for a possible new treatment for breast cancer and could help millions of people down the road. That in itself outweighs any possible chances of major side effects [for me]. ”

*Jennie, a subject in a breast cancer relapse prevention trial*

#### How do I decide?

Two key questions can help you make this important decision:

#### Do I have all of the information that I need to make an informed choice?

It's important to know as much as possible about the treatment and the trial requirements so that you can weigh all the factors. Get information about the trial goals, potential side effects, and what you'll be required to do.

Start by getting information from the research center that will be conducting the trial, but use other information sources as well. Keep in mind the research center may have its own motivations for conducting a trial, and its goals may be different from yours.

Get a second opinion about the trial you're interested in; ask your doctor, other health professionals, family, and friends.

#### How far am I willing to go?

Only you can answer the question of how hard you're willing to push yourself to get information required and to be willing to comply with the trial requirements. Your motivation to participate will influence how much you're willing to put yourself out.



# Find New Friends and Inspiration at the Clinical Research Volunteer Community



One of the highlights of clinical trials participation is developing friendships and sharing experiences, say many clinical trials volunteers. Participants enjoy the community spirit that thrives among people who are proactive in improving their own health and furthering medical science.

CISCRP's online Clinical Research Volunteer Community is a wonderful way to stay involved and keep in touch with new and old friends who feel similarly. The community connects patients, families, friends, and caregivers for support and inspiration. <http://community.ciscrp.org>



By joining this active online community, you'll enter a world of participation and connection. You'll be able to:

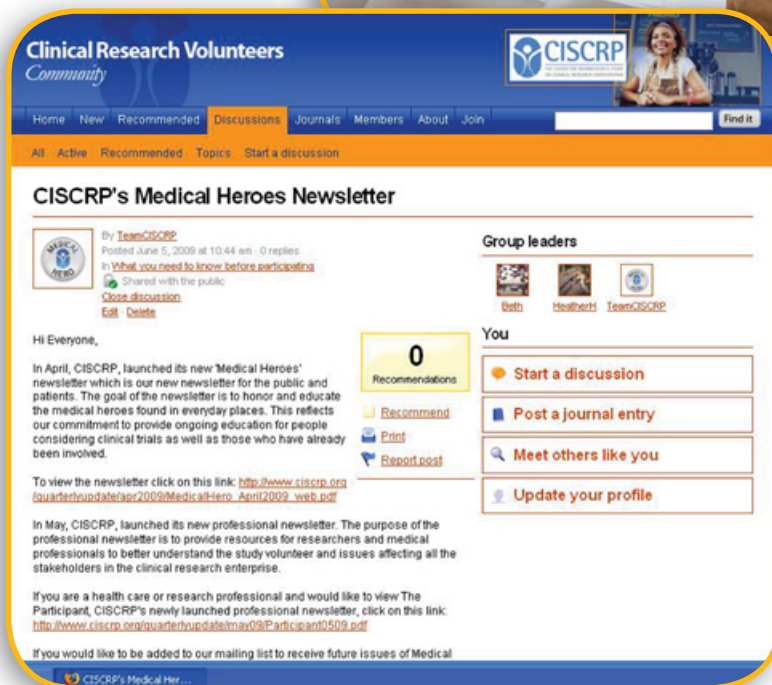
- Share your life, your struggles, your triumphs, and your questions with others
- Connect with people who have questions and concerns like yours
- Let friends and family know how you're doing
- Receive personalized updates and information about participating in surveys and clinical trials
- Join in health discussions
- Share your story via video so others can see it and get to know you
- Learn about conditions and treatments important to you
- Inspire yourself and others
- Post questions and comments on any topics relating to clinical trials, and read what others have posted.

You'll also get your own Guestbook, an exciting new feature.

The Guestbook lets you 'visit' a friend or member online, sign their guestbook, and post a friendly greeting or word of inspiration. When you access your guestbook you'll find a link to invite your family and friends to sign it. Every member gets their own guestbook. (The Guestbook is similar to the Wall on Facebook). You can see who has stopped by to visit you and wish you well.

If you are currently taking part in a clinical study, it's important to the integrity of the trial that volunteers should not discuss their participation experiences with other volunteers during the trial (for example, their reactions to the treatment; what treatment arm of the study they believe they are in; what to enter into their diaries).

Joining the Clinical Research Volunteer Community is free and takes less than a minute. Choose a screen name and password, and provide information about your gender, birth date, and location. If you prefer privacy, only your screen name will be visible. Or if you like being public, you can upload a picture of yourself so other members can get a better sense of who you are.



# What Happened with my Clinical Trial?



When a clinical trial ends, most volunteers are curious to know what came of their efforts. After spending time participating in a trial—and perhaps hoping for a new treatment—it's natural to want to hear about the results.

The Food and Drug Administration (FDA) recognizes that participants and the public have a right to know about clinical trial outcomes. As a result of the FDA Amendments Act (FDAAA) passed in 2007, companies that conduct trials have to do a better job of making results available and understandable to the public.

Starting March 2010, trials sponsors will be required to post expanded study results that include a lay summary—written for people who aren't scientists. These results will describe the data from the trial, the protocol (study design) and the quality control procedures used throughout the study.

Some steps have already been taken as a result of the FDAAA. Currently, the results of many completed trials are available to the public through sites such as [www.clinicaltrials.gov](http://www.clinicaltrials.gov), [www.searchclinicaltrials.org](http://www.searchclinicaltrials.org), and others. Those results include demographic and health-related characteristics of the patients who participated in the trial, including the number who dropped out and the number who were excluded from the analysis, if any, as well as the outcomes.



But starting next March, the studies published will be much more user-friendly.

There is still time before clinical trials in lay language are routine. Meanwhile, CISCRP will help by presenting another in a series of clinical trial results for people who want to know more about trials outcomes.

## Gleevec Clinical trials update

More than 10,000 patients participated in over 200 trials of Gleevec, made by Novartis Pharmaceuticals. The majority of patients had Philadelphia chromosome-positive chronic myeloid leukemia (CML). Many of these patients also had gastrointestinal stromal tumors (GIST), a very rare form of cancer that Gleevec targeted. Expected survival for most patients was about 5 years.

Gleevec clinical trials made important, life-enhancing improvements to cancer treatments. Volunteers who participated played a key role in developing a very effective treatment for leukemia and other cancers, which is now available to patients in over 90 countries.

“The vast majority of patients entered not to help register the drug, but under an expanded access program,” says Laurie A. Letvak, MD, of Novartis Oncology, East Hanover, NJ. “It had such fantastic efficacy that we had to make it available to patients before it became commercially available.”

## Key findings

- Gleevec was originally approved in May 2001 for treating advanced stage CML.
- In February 2002, Gleevec was approved for the treatment of GIST, and was shown to be very helpful in extending the lives of patients with advanced GIST. According to Letvak, “With GIST, we literally had people in hospice who responded and were still doing well about 5 years later.”
- Most patients in the early trials that tested Gleevec for safety showed some improvement at low doses of the drug. The first improvement seen was a reduction in white blood cell count, which showed that there was less disease present for the body's immune system to fight. Also, at a dose of 300 mg. to 400 mg., abnormal chromosomes associated with the disease began to disappear. This made it less likely that new disease cells would be produced.
- Later Gleevec trials showed that the drug was effective for Ph+ acute lymphocytic leukemia (ALL). At the end of 2005 Novartis filed for approval in the US and Europe for use of Gleevec in treatment of ALL.
- Because Gleevec showed potential in other subsets of patients, approval is being sought to use Gleevec in several other cancers, some rare.
- Thanks to the Gleevec trials, more cases of GIST are being diagnosed, which means that patients are getting treatment sooner.
- Gleevec trials prompted researchers to start examining genetic mutations that happen in the advanced stages of CML. Looking at these mutations helped them learn more about what happens as cancer progresses.
- Gleevec has enabled major long-term improvements in many patients' lifestyle. Patients report that they can travel, work, and lift weights with few or mild physical complaints.