



Patient Perspective

The stories below are from a series of articles created by CISCRP as part of their educational awareness campaign to increase public understanding that those who volunteer to participate in clinical trials are genuine "Medical Heroes."

Darby Steadman

Darby Steadman, a 38-year-old mother and homemaker from Seveva Park, MD, had a double mastectomy for breast cancer at age 34. After that radical operation, doctors told her there was less than one percent chance of the cancer recurring. So she turned her energies to family activities and raising her children, Liam and Audrey, now 9 and 7.

But in 2007, her life changed in an instant. Darby found a pea-sized mass under her left arm. After an examination, the oncologist gave Darby the worst possible news.

"I knew something was wrong," Darby recalled. "The oncologist came in and said, 'You have stage IV metastatic cancer.' It was pretty shocking."

In stage IV metastatic cancer, the cancer has spread to other organs.

Women with Stage IV cancer typically survive one to two years.

Darby heard about a clinical trial being conducted by Dr. Leisha Emens at Johns Hopkins School of Medicine. The treatment, which could lead to a potential therapeutic vaccine, is intended to help reengineer the immune system to attack breast cancer cells.

Darby was eager to participate in the trial. "When you have stage IV metastatic cancer, if there's a chance that a treatment could prolong your life or your child's life, it's not a hard decision to make," Darby said.

She became close with the other trial participants and developed a deep admiration for Dr. Emens' dedication. Darby felt so strongly about Dr. Emens' mission and efforts that she decided to organize other women and raise money for Dr. Emens' continued work.

"It is very expensive to run the study and keep it going," said Darby. "My poor doctor has to race around like a missionary to acquire funding, and beyond that, she has to find and acquire patients to be in the study."

With some of her former high school friends from Florida, Darby

held an event to raise money for Dr. Emens in December, 2008.

"We had a goal of raising \$2,000, and we had invited about 200 women from the neighborhood to come and participate in the event," she said. "In February 2009 we gave a check to Dr. Emens for \$14,520; we had received donations from more than 200 people."

Darby's trial has ended and she is now spending precious time with her family. She continues to see the other women in the group; the contact provides emotional support for all of them.

Because of her disease progress, Darby has had some deeply personal conversations with her children.

"Having Stage IV cancer has given me opportunities to have conversations with my children that you don't expect to have until they're much older," she says. "I've been able to share with my children my belief that I'm going to Heaven; that we're all in God's hands, and we're all to be joyful and thankful every day."

Stephanie Desmon

Journalists witness many dramatic encounters as they cover news, but

When clinical research participants are excused from the study team, they have a high willingness to participate in another clinical trial. But across the industry there is no follow up, and patients have no sense of connection or assurance of their contribution or value. Recent surveys have found that 79% of study volunteers report that they never hear from the research center once their participation has ended. Most study volunteers (86%) say that they want to receive information about what the research community learned from their participation. Only 14% of study volunteers believe that the industry will eventually disseminate all information – positive or negative – about an investigational treatment. This lack of responsiveness to clinical research volunteers is a serious issue that the industry can address through CISCRP's **Medical Heroes membership** program. Below is a brief description of the services that companies can make available to patients in collaboration with CISCRP.

Medical Heroes Membership

🕒 **Thanking Patients for volunteering in your clinical research study**

CISCRP will provide site staff with membership packets that they can personalize with their own handwritten signature. The message to the patient begins as follows: "It is said that the greatest gift is one which is given anonymously, giving when you do not know whether you will get direct personal benefit. This is the gift that you have given by taking part in clinical research. It is a brave and selfless act. Your decision to participate may not only bring you hope but also benefits public health and advances medical knowledge..."

🕒 **Providing patients the benefits of Medical Heroes Membership**

By offering the membership packet to patients, site staff can reassure them that, in return for their volunteering in a trial, they will receive the following:

- **Free bi-monthly newsletter called "Medical Hero"** which contains patient profiles (i.e., stories of patients who have participated in trials), ongoing education on the risks and benefits of participating in clinical trials, as well as recent *clinical trial results*

- **Invitation to attend a free public education program in their community** ("AWARE for All – Clinical Research Education Day") where they will be recognized as a Medical Hero and receive a gift
- **Online social network** known as "Clinical Research Volunteers Community" that connects patients, families, friends and caregivers for support and inspiration...
<http://community.ciscrp.org>
- **Assistance in locating clinical trials** through www.SearchClinicalTrials.org or by calling 1-877-MED HERO

All these services are provided directly to the patients by CISCRP. Companies incur no additional cost beyond the \$1 per patient for the membership packet itself. Patients have the opportunity to register for all these services from CISCRP by going online to www.MedHero.org or by calling 1-877-MED HERO.

🕒 **Recognizing your patients as a Medical Hero with a Lifetime Membership Card**

Study staff will be able to build patient pride by telling them they are now part of a community of millions of people like them who are heroes in the discovery of new medical treatments. The study staff can let their patients know they will be recognized and honored during the "National Medical Heroes Day" coming soon. Their Medical Heroes packet includes a pop-out card that the patient can keep in their wallet as an official member of the medical heroes community.

From the patient's point of view, concerns about follow up and recognition for volunteering will be addressed. From the industry's point of view, there is virtually no incremental investment in time with a patient who has completed a clinical trial. This is truly a win-win scenario where CISCRP and industry can collaborate to carry out the mission to educate the public about the clinical research process and promote greater understanding and appreciation of the role of the clinical research volunteer.

Questions? Please contact CISCRP at 781-326-3400 or info@ciscrp.org

for Stephanie Desmon, health and science writer for *The Baltimore Sun*, few were as heart-wrenching as the Johns Hopkins clinical trials she covered for women with Stage IV cancer.

“I’ve been a reporter for 15 years and this was the hardest thing I’ve ever done,” said Stephanie. “It’s one thing to have a friend who has breast cancer and go through it with them; but to go make friends with women who already have advanced stage cancer is a whole different thing.”

Stephanie grew interested in clinical trials while interviewing a Johns Hopkins physician working on an experimental treatment for sickle cell anemia.

“I wondered, what must it be like to be the first person to get a treatment, not knowing whether it’s going to work or not?” Stephanie recalled. “I can’t imagine being the first.”

Stephanie spent six months exclusively following the lives of four women enrolled in the trial conducted by Dr. Leisha Emens. One of them was Darby Steadman.

“I spent time with all of them; I went to one woman’s doctor appointments with her, and went to chemotherapy treatments with another,” said Stephanie.

“It was difficult to separate my emotions from theirs,” she says. “The day one of the women died was one of the hardest days in my career. There I was on the phone with her significant other, and he was crying and I was crying, and I was trying to ask questions I needed to know, to write her obituary,” she said.

As she grew closer with the four patients, Stephanie developed a powerful respect for their efforts.

“Although I write about clinical trials all the time, I hadn’t really thought about the process itself, and I think a lot of people still don’t think about it,” she said. “Thank goodness there are doctors like Dr. Emens

and other researchers taking these chances. And thank goodness there are women like the women in this study. It’s amazing that they were willing to donate a lot of time to something they didn’t know would help them or not, while thinking that maybe it would help their daughters. That’s a great thing to be able to do. I wish more people were willing to do the same.”

Stephanie’s series, which ran for six days in October 2008, prompted heartfelt letters of thanks from women readers who had advanced breast cancer. The series was a finalist in the Scripps Howard Foundation National Award in the Human Interest category.

Daisy Nanton

Daisy Nanton, a sprightly 87-year-old from Baltimore, MD, watched with dismay as cancer ravaged her relatives over many years. In an effort to avoid the same fate, she began taking part in clinical trials. “I’m from a cancer family,” said Daisy. “My mother and five of my six siblings had cancer. I didn’t, but I’ve had some scares.”

A mother of five and a grandmother of seven, Daisy has been a clinical trials volunteer for the past 15 years. She describes herself as “kind of a hypochondriac,” and partially credits the trials for keeping her in good health.

“When I was 21, my mother’s younger sister had a little lump on her breast but would not go to a doctor,” said Daisy. “When she finally went, she was diagnosed with a very aggressive form of cancer. She died very soon after. It was terrible.”

“That put me on the path of going to doctors,” added Daisy.

Daisy had moved to the US from her home to Monserrat, an island in the Caribbean, and eventually wound up in Baltimore. Money was tight, so she went to health fairs to get free blood pressure checks

and other screenings. One year, an investigator at Johns Hopkins University in Baltimore asked her to join their study on women’s health and aging.

“Of course I was glad to join,” Daisy said enthusiastically.

The Johns Hopkins Women’s Health and Aging Study (WHAS I) lasted five years. When that study ended, Daisy participated in WHAS II, whose goal was to learn about preventing or delaying the onset of limitations in physical function in older adults. Daisy is now involved in WHAS III, which evaluates the role of inflammation, hormones, micronutrient deficiencies, and other physiologic systems in the development of disability and frailty.

Daisy also participated in the Women’s Health Initiative, established by The National Institutes of Health (NIH) to address the most common causes of death, disability, and impaired quality of life in postmenopausal women.

Although Daisy was excited about volunteering for trials, some of her friends and family were incredulous.

“When I started, I had a lot of opposition,” says Daisy. “People said, ‘Another test? Not again!’ One woman thinks I’m crazy for going to so many doctors. But if you wait for something to be wrong, it could be too late.”

Daisy appreciates the medical attention she gets in the WHAS III study, plus she credits it for helping to keep her healthy.

“The study has been very, very good,” she said. “You benefit from it. If there’s any health problem, they find it right away.”

“And from an unselfish point of view, I’m helping my children and grandchildren and other women.”

That cheery attitude and pro-health outlook have helped make Daisy as chipper and active as she is. “I’m not doing too badly for someone 87 years old,” she laughed. ■