



## Medical Hero in the Spotlight

# Clinical trials inspire hope in Rosa's battle for life

**R**osa Small knew that something was wrong. She had always performed regular breast self-examinations and had never noticed anything unusual until one day, at age 62, she felt a lump in her right breast. "My only symptom on self-exam was the lump, and it was not sore," says Rosa. At that point, Rosa could not have predicted that she would soon put her faith in clinical trials to help prolong her life.

Disturbed about her finding, Rosa went to her primary care physician, who confirmed the lump. Rosa immediately went to a radiologist, a surgeon, and an oncologist, who confirmed her worst fears. Rosa was diagnosed with invasive adenocarcinoma of the breast, which is a malignant tumor that spreads beyond where it initially developed and invades healthy tissue. "I have Triple Negative Breast cancer," says Rosa. That type of breast cancer is considered more aggressive and less responsive to standard treatment.

Up until then, Rosa's life in Durham, NC, was happy and active in the town where she lived with William, her husband of 49 years. She had retired from the Durham Public Schools as a media coordinator, and now had a satisfying job as an events manager. Learning she had cancer threw Rosa's cheery existence into a tailspin. "I felt as if my life was almost over, and I desperately wanted to live," says Rosa.

As Rosa struggled with her illness, her oncologist suggested a new treatment that he thought might be promising. The treatment was part of a clinical research study. Rosa was determined to keep fighting, so she learned more about the study, and went through the informed consent process.

### Willing to take the risks

She knew that there might be risks involved with taking part in a clinical trial; but she also knew it might be her best bet. "Cancer is scary and it makes you humble," says Rosa. "I had heard about people who had been in trials and they had gotten worse. However, I spoke with another person who had been in clinical trials

and she was very positive. I was somewhat apprehensive, but I had faith that things would work out."

The trial took place at the Morris Cancer Clinic at Duke University in Durham, NC. The treatment being tested was not yet available on the market. Rosa was one of 100 participants with a similar condition.

Rosa participated in a number of trials, each lasting from 2 weeks to 5 months. "The first clinical trial lasted 5 months until I had some side effects that caused me to stop the study," says Rosa.

Taking part in clinical trials helped Rosa feel that she had some control over her disease. "I also had more treatment options than the standard treatments."

In addition to getting the best possible care, Rosa also appreciated the warm and solicitous treatment from the clinical site staff and researchers. "The most positive part of the trial was the amount of attention that you get in a study," says Rosa. "The people conducting the trials were very much involved with my care and were willing to speak to me at any time."

While Rosa's most recent clinical trial has ended, she plans to enter another clinical trial when her oncologist suggests one. "I still have metastatic breast cancer, and the tumors have moved to my lungs," says Rosa.

Yet the positive spirit that has bolstered Rosa through a happy, industrious life is still burning fiercely. "I am optimistic about my future, and I feel that I will be managed for many years," says Rosa.

"I would ask anyone to take part in research trials, as it can help you and possibly future generations," says Rosa. For her and thousands of other clinical trial participants, the lifesaving developments that can come from clinical trials keep them hopeful and looking toward the future.

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# Can you bring clinical trials awareness to your community?



Theda Martin, a 61-year-old nurse from New Albany, IN, bubbles over with enthusiasm about her work. Convinced that most people knew little about clinical trials and the important medical developments they produce, Theda held a 'grass roots' community education evening at her local church. Through her own initiative, Theda gave a talk about clinical research that opened the eyes of her fellow churchgoers.

Theda, a quality and compliance manager with Kforce Clinical Research (which provides staffing to pharmaceutical companies), had worked as a research site coordinator. "I love what I do," says Theda. "My life is my work."

Theda is an active congregant with the Harvey Browne Presbyterian Church in Louisville KY, just about six miles from New Albany. She's also a member of the church's Wellness Committee, which presents a different speaker each month after the Wednesday evening services. "Our committee is always looking for a presentation that would be interesting to people who attend the Wednesday services," says Theda. "Most of the presentations have been disease-related, about subjects like Alzheimer's, heart disease, and stroke, although we have also had other subjects."

Church is often a place for inspiration, and Theda was struck with the idea that church members would be interested in hearing about clinical trials. For about a year, Theda toyed with the notion of giving a talk to the group. Finally she proposed it to the Wellness Committee. They responded with enthusiasm.

Theda thought that creating a presentation might be daunting. But it turned out to be much easier than she anticipated. "I started just throwing together some slides and then I learned that CISCRP had material they made available to volunteer speakers," says Theda. "They had a PowerPoint presentation and background material that I could use." The ready-made mate-

rial simplified the task of putting together a professional-quality presentation and handouts.

While some speakers struggle with stage fright, that wasn't a hurdle for Theda. "I'm used to doing presentations as part of my job as trainer, and besides, I love to talk," Theda laughs.

The presentation was a hit. Turnout at the Wednesday night presentation was excellent, as was the audience response. About 25 people gathered to hear Theda's talk. "It was well received and was really great," says Theda. Theda's friend, a coordinator at the University of Louisville helped with the presentation and was on hand to provide support and questions.



Several attendees stayed afterwards to talk more. "Usually people just come to the meeting and leave," says Theda. "But in this case, people were staying and asking for more information. I think they were very engaged."

Theda's successful evening, the warm audience response, and the valuable information she provided, illustrates how 'regular' people can spread the word on clinical trials awareness in their own communities. "It's a wonderful and worthy thing to do," says Theda. "There doesn't always have to be a big organized event that takes the whole day. Anyone can do this."

CISCRP welcomes those who would like to do volunteer community presentations about clinical trials. CISCRP can provide a PowerPoint presentation template with background information and statistics, which volunteers can customize to add their own information and experiences. Also available from CISCRP are educational brochures that can be distributed to the attendees.

To learn more about doing a presentation or volunteering, go to <http://www.ciscrp.org/professional/speaker.php>



## Join us at AWARE for All

Have you attended an AWARE for All- Clinical Research Education Day in your community? CISCRP's popular AWARE for All- Clinical Research Education Day jumped to a new level of visibility and recognition when the National Cancer Institute (NCI) endorsed and took an active role in the Baltimore AWARE event. The National Cancer Institute is a division of the National Institutes of Health (NIH).

The success of that partnership inspired the NIH to continue to partner with CISCRP for future AWARE for All days. "Partnering with the NIH lends a lot of credibility to the AWARE for All program," says Jill McNair, National Director, AWARE for ALL at CISCRP. "People trust the NIH. It means a lot to have them involved."

CISCRP looks for key partners in prospective AWARE for All locations. The partners comprise a vital element in enabling the AWARE for All to create a successful event in that city. "Once we begin to build a foundation of community partners, we build momentum," says McNair. "As a result of gaining new partners, the number of participants at each event typically goes up as the years progress. We expect turnout to be even greater in 2010."

Increasing public awareness about clinical trials is one of the primary goals of the NCI's Office of Communication and Education. This goal dovetails perfectly with CISCRP's own mission. For the Baltimore AWARE for All event, NCI staff provided a newly-developed methodology tool to measure the attendees' knowledge about clinical trials before and after taking part in the AWARE for All day. Additionally, the NCI promoted their participation in the event and made the following statement of support: "CISCRP AWARE for All day provided an excellent opportunity to explore the feasibility and effectiveness of working across NIH and with community partners on an established awareness campaign." The NCI further announced that "The national effort complements the local, grassroots organizational effort by connecting government-funded researchers to community organizations who represent the area populations who are typically under-represented in federally-funded research."

For this reason, the NCI invited other NIH divisions to take part in the AWARE for All day. Those that joined the effort included the National Institute of Aging, the National Institute of Allergy and Infectious Diseases, and the National Library of Medicine.

CISCRP is delighted to continue our collaboration with the NIH on clinical research awareness days. AWARE for All's mo-



mentum has flourished since its inception in 2005, and in 2010, two new locations will be added: Nashville, TN, and either San Francisco or San Diego, CA.

Contact us for more information on an AWARE program near you. Hope to see you soon!

*Upcoming AWARE for All event:*  
**AWARE for All Nashville**  
**February 20, 2010**

**Click here to register**



# Clinical Trials Amendment

*The following press release from the office of US Senator Sherrod Brown announces the introduction of a bipartisan amendment to expand and protect access to clinical trials (Amendment 2871). This proposal would protect patients' health care coverage while an individual is enrolled in clinical trials. This amendment has since been included in the Senate's version of the Health Care Bill. Prior to the filing of Amendment 2871, CISCRP's President and CEO, Diane Simmons, and CISCRP's Board Chair, Ken Getz, conferred with Senator Brown's legislative aide David S. Mitchell.*

December 16, 2009

**D** Washington DC- U.S. Sens. Sherrod Brown (D-OH) and Kay Bailey Hutchison (R-TX) announced a bipartisan amendment to the health reform bill which would protect access to clinical trials for patients with life-threatening diseases. The amendment would prohibit insurers from dropping a policyholder's coverage if the patient chooses to participate in a clinical trial and from denying coverage for routine care that the plan would otherwise provide. The amendment is cosponsored by Sens. Al Franken (D-MN), Sheldon Whitehouse (D-RI), Arlen Specter (D-PA), Benjamin Cardin (D-MD), and Bernie Sanders (I-VT).

"Americans with life-threatening diseases should be able to spend time fighting their illnesses, rather than battling insurance companies," Sen. Brown said. "This amendment prevents insurance companies from denying patients' access to routine medical care just because they are enrolled in a clinical trial. If we're going to make medical breakthroughs, we need to encourage participation in clinical trials, not put up barriers. Patients with chronic conditions should not have their health coverage jeopardized if they choose to enroll in a potentially life-saving trial."

Video footage of Brown speaking on the Senate floor in support of the amendment can be found [HERE](#) (footage takes a few moments to load).

"Maryland's facilities, including Johns Hopkins, the University of Maryland, and the National Institutes of Health, are home to the world's leading medical researchers. For many patients with serious illnesses, clinical trials are their only hope. They should not be denied the benefits of cutting-edge therapies and treatments

because an insurance company refuses to pay for routine costs, such as laboratory services," Sen. Cardin said. In 2000, as a member of the House Ways and Means Committee, Cardin led the bipartisan effort to secure Medicare coverage for routine patient costs associated with federally-funded or reviewed trials.

"I am pleased to join Senator Brown in cosponsoring this amendment," Sen. Specter said. "Clinical trials are vital to advancing research on treatments and cures to serious illnesses that affect so many Americans, and patients should be able to access these trials without having their insurance company reduce or limit their coverage."

Clinical trials often offer cutting-edge therapies that are not available through traditional methods. These experimental treatments save lives and advance research. However, many health insurance policies discourage enrollment in these trials by refusing to cover trial participants' routine health care, those basic services unrelated to the trial and justly owed to the premium-paying policyholder. According to The Ohio State University's Comprehensive Cancer Center, an estimated 20 percent of patients who attempt to enroll in clinical trials are denied coverage by their insurance. These patients are often prevented from exploring clinical trial options because they risk losing health care coverage for routine services like X-rays, blood tests, and doctor visits.

Low participation rates in clinical trials undermine research and medical advancements. Only about two percent of Americans participate in clinical trials annually and only six percent of people who suffer from severe, chronic illnesses enroll in trials. These low participation rates make it harder to conduct timely trials. In fact, delays in patient recruitment for clinical trials account for an average of 4.6 months lost per trial. Nearly 80 percent of trials run over schedule by more than a month, and only six percent are completed on time.

Brown and Hutchison's amendment (#2871) is modeled on existing Medicare policy and on more than 30 state laws and regulations that already guarantee patient access to clinical trials. Amendment 2871 would apply to all insurance products, including those offered in the Federal Employees Health Benefits Program, and to all clinical trials that treat cancer or other life-threatening diseases. Brown introduced similar legislation, the Cancer Clinical Trials Act, in February 2009.

