

# IUSCC PINK

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Dear Friends,

I feel privileged to join the strong department of medical oncology here at the Indiana University Melvin and Bren Simon Cancer Center and in particular the IUSCC Breast Care and Research Program. I strongly support the beliefs that breast cancer requires the combined efforts of a dedicated group and that the cure for breast cancer lies in research. I am proud to be joining a Breast Cancer Program that is committed to conducting well-designed clinical trials to answer important questions about breast cancer and that will ultimately lead to better health for cancer patients (see the following pages).

In the words of my mentor, I believe that "Cancer is about living, not dying." I hope to join the fight against breast cancer by caring for patients, working to develop a cancer survivorship program and launching cancer support organizations in the community. I completed a residency and chief residency in internal medicine at Rush University in Chicago and a medical oncology fellowship at the University of Washington and Fred Hutchinson Cancer Research Center in Seattle. While there I spent time researching biomarkers to detect breast cancer recurrence and breast cancer survivorship issues. Along with the Breast

Care and Research team, I hope to begin a few new projects focused on survivors. One of which is a Survivor clinic for women here at IUSCC. This clinic would focus not only on continued cancer surveillance, but general health and wellness. The multidisciplinary approach that is used in cancer treatment will also be used to develop individualized wellness plans.

Oncology is a profession that requires special energy, patience and passion. The patients I have been lucky enough to care for have provided me continued inspiration and motivation as my true passion in medicine is patient care. I am excited to become part of such a wonderful team and continue to join the fight against breast cancer.

**-Aparna Jotwani, MD**

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# My Bottom Line

By Rosanne Altstatt



Usually, I put on a dark power suit, carry a leather briefcase and metaphorically pound on the table when I advocate for something. It is really hard to do this while sitting half-naked on an exam table, its white paper crunching beneath me and my feet dangling in the air. So now that there is no sign of cancer in my body and I am fully dressed, both literally and in the sense of no longer being psychologically unclad while in treatment, I am in a better position to advocate for more transparency and a forthright discussion about patients and value – moral and financial – in clinical trials.

In 2007 I entered a clinical trial at IU because I wanted the drug Avastin. Its market price is tens of thousands of dollars, and since Avastin was not FDA approved for breast cancer at the time, there was hardly an insurance plan out there that would pay for it. I was fortunate to have been eligible for a study in which it was made available for free.

But the story does not end there. An exchange was made for that drug and the values of everything involved should be made more clear. I got the Avastin, which everyone involved hoped would improve my progression-free survival and perhaps even my overall survival. In exchange, the cancer center's research labs as well as the pharmaceutical companies received access to my body as an object of study and my

medical data. The value of exactly what a patient is giving and getting in that exchange is rarely addressed beyond the often cited knowledge that she is doing her part to contribute to finding a future cure for cancer.

From the start it should be said that due to its prohibitive cost, I would not have been an Avastin customer. In fact, for the leg of the trial I was in, patients also had to take an oral chemotherapy, Xeloda, because the trial tested the efficacy and toxicity of these two drugs together. There is no generic form of Xeloda and it is very expensive. This was not covered by the trial, but if a patient wanted the Avastin, she had to buy the Xeloda.

There are many more costs involved in a trial apart from the drugs. Everything around Avastin would still be invoiced: the doctor's visit, the blood tests before each infusion, sitting in the chemo chair ... I cannot itemize the long list of costs without having to look up the many codes in my piles of "explanation of benefits" statements from the insurance company.

Patients must understand that their medical data is also valuable. In the consent I signed for the trial, I agreed to give every party involved access to my past, present and future medical data. A trial is conducted in order to study medical data, so it is reasonable that they have access to it. Today's data will help make new and better drugs for tomorrow, and they may need my future data to show how the drug performs long-term.

I feel lucky to have been a part of this trial, but that does not detract from the fact that this is not a good system. Our health care system in general is morally wrong because an enormous amount of money is being made off of sick people, driving some to make choices like to either pay their mortgage or their medications. Patients are constantly receiving the message that they have no value, that they are driving up the insurance premiums for healthy people and bringing down our country's work productivity. It is too easy as a patient to slip into that mindset. First, one must recognize one's great value as a human being, whether sick or healthy. Second, one must recognize that a sick person is also a valuable customer to many parties. Patients must keep these two things in mind and use them to create a position of strength in order to advocate for themselves.

Granted, not every patient wants to sift through all of the information because just having cancer is overwhelming to begin with. But I am certain that many do want to understand. Only then can they and their families advocate for things like never having to even think about a financial burden when they are already offering so much to a clinical trial. In my case, my medical team worked it out with the insurance company so that almost everything would be covered. It ended up costing much less than it could have because I spoke

up. There is no question that oncology doctors and nurses are truly invested in doing the best for their patients. Otherwise, they would probably pick an easier field of medicine. All of my local doctors had recommended I enter an IU Avastin trial in order to kill as much of the cancer as we can before it kills me, and it was essential to keep my eye on that goal. That was my bottom line.

*Congratulations  
Congrats!*



It's a Boy! Congratulations to Drs. Bryan and Kim Schneider on the adoption of their little bundle of joy.

*Cole Matthew  
Born: December 13, 2009  
Weight: 7 lbs 10 oz Length: 20.5 in*

This winter has been a busy time for our team outside of work. Dr. Schneider is learning the joy and sleeplessness of being a new dad, while IUSCC Pink Editor Casey Allen (now Bales) escaped the cold of Indiana for a beautiful wedding in Negril, Jamaica.

*Brandon & Casey Bales,  
Married November 7, 2009*



# Not Letting Cancer Stop Me

By: Terry Farrer

Experimental drug studies, where would I be without them? On Maundy Thursday (the Thursday before Easter) in 1993 after a breast biopsy I found my life spinning out of control with the diagnosis that I had breast cancer. How could that be? I had no family history or any of the risk factors until the doctor said I had the greatest risk factor of all. I had breasts! Wow! I know that a lot of the women in my area immediately got on the phone and scheduled mammograms because of my diagnosis. Drs. Schmidt and VanNatta surgically removed my cancerous left breast and reconstructed a new one all at the same time. There was lymph node involvement so I knew I was in for further treatment. At this time, my three sons were 14, 11 and 4 years old. My 4-year-old really had no idea what was going on. He just knew mom was hurting. One particularly tough day, he pushed himself away from the dinner table and said he would be right back. He came back with two balloon bouquets from my bedroom. He plopped them down by my chair and then took each balloon in his hands and said, "read it." They said things like, "Hang in There, You Can Do It, Get Well Soon." I scooped my little son into my arms and thanked God for the love He was showing me through this child.

*When asked to do a clinical trial, I knew I had nothing to lose.*

Dr. Sledge then became my oncologist and led me through six rounds of intensive chemotherapy. As I was losing my hair, I kept telling myself that I was losing my hair to save my life. I was so excited to finally get the last treatment and have the cancer behind me. I took Tamoxifen for five years and felt like I had beaten the cancer. My life went on.

Then in 2002 I had some minor gynecological problems, but I knew I needed to get it checked out. A mass was found growing on my right ovary. Blood tests ruled out ovarian cancer, but my GYN wanted to remove the ovary just in case. I am glad she did, as it turns out breast cancer cells had hung around and resurfaced on my ovary. I was scanned, but cancer was not found anywhere else. CA 27/29 blood tests indicated that I had cancer activity. I was started on Femara and then Faslodex. Neither of these treat-

ments worked for the long term. In December of 2003, it became apparent that I would need to do chemotherapy again. A mass had showed up on my other ovary. Anita Rush-Taylor, RN, came to me and asked if I was interested in participating in an experimental drug study. I knew I didn't have anything to lose and could gain a lot, not just for myself, but for the women who would come behind me. I did all the extra tests necessary to enter the study and then hoped and prayed that I would qualify. Fortunately, I did. I started the study the day after Christmas. All my family came and stood by me. It had been 10 years since I had to undergo such strenuous treatment. I got Taxol every week for three weeks and the fourth week I got to rest. On the first and third weeks I also got the experimental drug. Eventually, I learned it was the drug Avastin. I was scanned every three months to make sure the tumor was shrinking and not growing. The first scan showed it was working! I was elated!

The side effects of the treatments were loss of hair, immune system suppression, loose fingernails and protein in my urine. As a part of the study protocol, I had to do 24-hour urine collection every month. I got quite good at it. It was during the first four months of the study that I received a port. It has been a god-send. I did all I could to cope with the side effects. When my fingernails got sore and loose, I just wrapped them with bandages. With protein in my urine, I drank lots of water and took the blood pressure medicine. As different side effects came up, I would tell myself, "This too shall pass!" And it did! Yes, there were challenges, but I would do it all again.

I kept working. I didn't pull off the road of life, I just turned a corner. I got a wig and named it Julia. When it needed to be washed and reset, I called my friend and hairdresser and asked her if "Julia could come over for a sleepover!" I had to keep a sense of humor. When asked to do a clinical trial, I knew I had nothing to lose. God gave me the strength I needed each day. I had a support group of friends to drive me to and from treatments. It took a whole day from their schedule to do that for me. This enabled my husband to keep working and not have to take time off. There were special friends who reminded me that God loved me very much on the days I was really down.



*Steve and Terry Farrer with their three sons and two daughter-in-laws.*

I decided I wasn't going to let cancer slow me down. I had treatments on Fridays so I would have the weekend to recuperate and then it was back to work on Monday. I had plotted on the calendar when I thought the last of my treatments would be. However, since I was doing so well, the doctors wanted me to continue on Avastin. They decided I didn't need any more Taxol so I was able to stop that and let my immune system return to the low end of normal. I was driving from Logansport, Ind., two hours to IU Simon Cancer Center in Indianapolis. The trips were getting tiring. I really didn't want to continue, but I came to grips with the fact that this was a chronic disease, and I would have to be in treatment for the rest of my life. I began looking at my health situation like someone with heart disease or diabetes. This is what I have to do.

After being on Avastin for a total of 26 months, a CT scan showed that the tumor on my left ovary was growing. The Avastin had lost its effectiveness. Luckily, the cancerous ovary that had been removed revealed that I was Her2 positive and a candidate for Herceptin. I knew from Dr. Sledge that there were studies being done combining the drugs Avastin and Herceptin. With the Avastin in my system Dr. Sledge was confident that we would see good results when we stopped the experimental study and switched to Herceptin and Taxol. So, for another six months I took Taxol and Herceptin. Within six weeks, the scans could not find any sign of cancer. I of course was elated!!

That was in 2006. Here it is 2010, almost 17 years since I was first diagnosed. I still continue to get a half-hour infusion of Herceptin in Indianapolis every three weeks, and have a CA 27/29 blood test every three months.

As mentioned earlier, I have come to grips with the fact that I will have to be in treatment for the rest of my life. I am grateful to Dr. Sledge, Anita Rush-Taylor, RN, and God for getting me into the original study. I have seen my sons all grow up and graduate from high school. Two of them have graduated from college and are now married. My youngest is almost 21 and a sophomore at Purdue. I have experienced so many blessings in spite of

having breast cancer. Finally, I couldn't have made it through all the treatments, scans, and blood tests without the loving support and concern of my husband, Steve. We will celebrate our 36th anniversary this summer. I can remember asking Dr. Sledge if I was terminal. He said, "We are all terminal!" How true! I decided early on that I was going to go on living and not let cancer stop me. I also knew that I would do whatever I could to increase my odds of surviving cancer. For me, that meant enrolling in an experimental drug study. Maybe that is what it will mean for you too.

## *Featured Web Site*

Are you struggling to keep everyone update about your current condition or treatment? CaringBridge.org offers free cancer support web sites. The web site includes a journal for sharing news and updates. Visitors can leave messages of love and encouragement for the patient and caregiver in the guestbook. This is a great way to share your journey with your family and friends and not be overwhelmed with phone calls and emails. Visit [www.caringbridge.org/cancer](http://www.caringbridge.org/cancer) to start your own blog web site today.

# How Much Do Clinical Trials REALLY Cost?

By: Kerry Bridges, MBA, RN, CCRC  
IUSCC Adult Clinical Research Office Administrator

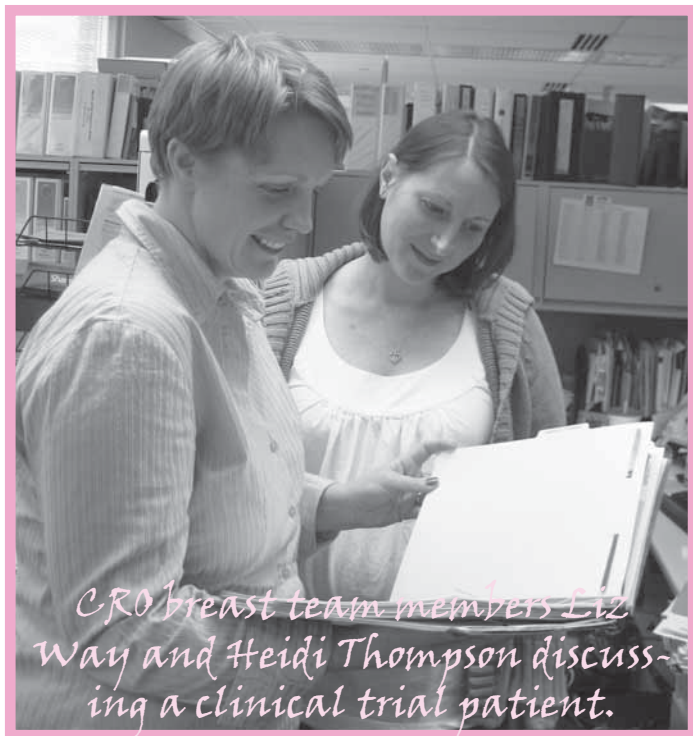
The IU Simon Cancer Center Clinical Research Office manages an average of 163 clinical research protocols (clinical trials) a year. These studies provide opportunities for oncology patients to receive investigational agents (new drugs that have not received FDA approval and are, therefore, not available for standard of care treatment), off-label drugs (FDA approved drugs but not for this indication or disease), investigational devices (newly developed technologies such as imaging and therapeutic radiology) and prevention or "quality of life" (supportive care) trials just to name a few. There are also epidemiologic and observational trials

So who pays for all this staff and effort? IUSCC is a National Cancer Institute (NCI)

designated Cancer Center, therefore, we do receive some federal funding to help support our research at IU. Fifty-eight percent of the Clinical Research Office income in 2009 was from pharmaceutical and biotech support, often referred to as "industry" supported.

It takes an average of 90 days or three months to open a clinical trial at IUSCC: the first patient is enrolled within a median of 30 days (median time to open a study and enroll a patient at the 17 other NCI designated Cancer Centers was 4.5 months in 2008). To be able to offer a patient a clinical trial, many processes have to happen in those four plus months: Recent data show anywhere from 370 to 481 steps take place. For every one day delay in the development of a clinical trial for a drug that ultimately becomes successful, it costs the pharmaceutical company between \$800,000 and \$5.4 million. So, time truly is money in their working environment.

When trying to determine a budget for a clinical research study conducted at IUSCC, the finance staff reviews the protocol for research related tests, visits and procedures. Only those tests, visits and procedures that are not standard of care are billed to the research budget. Standard of care is determined by Medicare and standard practice by oncologists locally and nationally. Insurance generally pays for standard of care which includes FDA approved drugs or treatments for that particular disease. Clinical trials are designed to follow standard of care but with an additional research component be it drug or procedures. Additional procedures require safety testing and monitoring by the study team: that cost is charged to the sponsor not to insurance nor the patient. The investigational agent is provided by the sponsor free of charge to the patient. The study staff is paid by the sponsor for their additional work. The average cost per patient to the study sponsor varies depending on the complexity of the study. At IUSCC the costs range from approximately \$3000 per patient up to \$40,000 per patient for a complex study. The average study takes two to three years to enroll enough patients to determine if it's "worth" pursuing to the next step or phase of a trial. Worth being defined in this instance as "Is it safe and showing a benefit and is it



CRO breast team members Liz Way and Heidi Thompson discussing a clinical trial patient.

that may also include healthy populations. In 2009, 1,925 patients were treated on oncology studies conducted at IUSCC. IUSCC employs more than 200 researchers including clinical and basic scientists.

The Clinical Research Office at IUSCC has a staff of 55 employees including research nurses, clinical research specialists who collect all the data, research lab personnel, regulatory oversight staff and finance personnel. The responsibility of this office is to ensure patient safety by following the IU-IRB approved protocol, including collecting all side effects and following federal and state guidelines.

better than the standard of care?" There is also a cost to opening trials that do not enroll any patients. For 14 cancer centers studied, that cost equates to \$81,000 a year. For pharmaceutical companies, they may spend \$40,000 to start a trial at a cancer center where no one enrolls.

It is reported to cost approximately \$1 billion for pharmaceutical companies to bring an idea to market for a new drug. Approximately \$400 million is spent in the preclinical stages of drug development: that is before the drug is ever tested in humans. Another \$500 billion dollars is spent in the clinical trials phase. In cancer therapy development, there is only a 20 percent probability of a drug receiving approval by the FDA. The average process of piloting a potential treatment from discovery through approval takes 14.2 years. Cancer treatment is moving toward a personalized approach: therapy based on your genetic make-up. It is innovative and expensive and in the United States, but we have been willing to pay high prices for new technology through research and development.

The physicians wish is to provide the best treatment available. We often state, "It takes a village to enroll a patient on a clinical trial". Our primary objective at IUSCC is to conduct good research. We want to offer the patient the best treatment available with the best care. We all play a role in understanding your unique needs and presenting all treatment options available.

# Breast Cancer & A

## **What would you like to see in the proposed health care from the government for breast cancer patients? Especially cost of prescriptions?**

-Currently a serious illness or injury is one of the leading causes of bankruptcy in the US – that's wrong. We are the only industrialized country that doesn't guarantee all citizens basic health care at an affordable cost – that's wrong. Providing basic coverage for all should be the goal.

## **What can we do to get insurance companies to pay for the Oncotype DX test?**

-Oncotype Dx is an approved test for women with ER+ tumors that don't involve the lymph node. While some companies have initially denied coverage, appeals have been successful. Genomic Health (the company that developed the Oncotype Dx test) has been very helpful and appealing decisions.

## **Does the removal of our lymph nodes lower the possibility of lymphedema?**

-Removal of lymph nodes is one of the factors that contribute to the development of lymphedema. The more nodes removed, the greater the chance of lymphedema.

## **In relation to diet, what is the new research or information about protein consumption?**

-I (Dr. Kathy Miller) am not aware of specific information about protein. Research continues to show that a diet lower in saturated fat, with more focus on fruits, vegetables, and whole grains, may decrease risk of breast cancer.

Nearly 1.5 million new cancer cases are diagnosed each year in the United States. Although improvements in detection and treatments have significantly improved five year survival rates over the past 30 years, we need to do better. Clinical trials are a central component in efforts to improve treatment options and quality of life. But, this comes with a considerable cost. Cancer Care accounts for ~5 percent of health care spending and is expected to increase as a result of new treatments and medical technology and an aging population. According to the National Institutes of Health (NIH), \$89 billion was spent on cancer care in 2007, with an economic burden totaling \$219.2 billion.

## ARE YOU INTERESTED IN LEARNING MORE ABOUT BREAST CANCER?

Sign up to receive the *IUSCC Pink* Newsletter

Name: \_\_\_\_\_ \*E-mail: \_\_\_\_\_

Street: \_\_\_\_\_ City/Zip: \_\_\_\_\_

\*Newsletters will be sent by e-mail when applicable.

Return to Casey Allen at:

Walther Hall (Building R3) - Room C246  
980 W. Walnut St.  
Indianapolis, IN 46202-5126



**INDIANA UNIVERSITY**

MELVIN AND BREN SIMON  
CANCER CENTER

Or send an e-mail to [calallen@iupui.edu](mailto:calallen@iupui.edu) with the above information.

Do you have a story idea or just something to say about a story you've read in *IUSCC Pink*? Tell us about it! Would you like to share a personal experience? Contact us via e-mail [calallen@iupui.edu](mailto:calallen@iupui.edu), call 317-274-0594 or send mail to the address above.

Past editions of *IUSCC Pink* can be viewed at the IU Simon Cancer Center Web site, [cancer.iu.edu](http://cancer.iu.edu), by selecting breast cancer in the cancer type section (<http://cancer.iu.edu/programs/breast/iuccpink/>).