

# Constellation

A Newsletter for All STAR Participants



## STAR Results Available in April 2006!

*D.L. Wickerham*

D.L. Wickerham, MD  
STAR Protocol Officer & NSABP Associate Chairman

**Congratulations!** We are reaching a major milestone in the STAR study and we couldn't have done it without you. The initial analysis of the data is going well and being compiled as I write. We are hoping to share the initial STAR results with you by late April 2006. If this occurs, you will also learn which arm of the trial you were on –tamoxifen or raloxifene. We know you will wonder what you should do at that point and we are in the process of working out the details. Your principal investigator and program coordinator will be well informed by us and will be able to

counsel you at that time. It is an exciting time, but we need your help now more than ever. We need each STAR participant to keep your regularly scheduled appointments with your STAR personnel, submit all information such as yearly mammograms and other valuable information to the STAR site, and make sure that your contact information is up to date. We also need to stress that the trial does not end even though you know what arm of the trial you were on. We made a commitment to follow participants and you will still complete the tests required by the study protocol

through seven years and current plans are to keep track of your health status for life.

Below is a timeline of current and proposed activities. As you can see, April is going to be a very busy time for the NSABP and your STAR site. We will make every effort to see that you learn the results of the trial from your STAR staff before they are reported in the news. However, in this fast paced media environment of 24 hour news cycles, this may not occur. If this should happen, please be patient and wait for your STAR staff to contact you. They will make every effort to do so in a rapid fashion.

### December 2005

The initial comprehensive analysis of STAR data will commence.

### April 2006

STAR results will be presented to the Data Monitoring Committee (DMC), an independent review board that oversees STAR. The DMC will advise the NSABP as to whether participants should be told what drug they were on and to publicly release results whether or not to unblind.

If the DMC's recommendation is favorable, which we anticipate that it will be, the NSABP will begin the process of notifying AstraZeneca Pharmaceuticals, Eli Lilly Pharmaceuticals, and all STAR sites who in turn will contact participants.

As the participants are being notified, the NSABP and the National Cancer Institute (NCI) will release the results to the public.

Despite our best efforts, some STAR participants may learn the results through the media. Please be patient and wait for your STAR staff to contact you. Some sites have hundreds of women in the study.

### April 28-May 1, 2006

NSABP Group Meeting, Denver, Colorado  
STAR results will be presented to the STAR investigators who will be attending the NSABP Group Meeting.



## What Happens Now?

Victor G. Vogel, MD, MHS  
STAR Protocol Chair

STAR began to enroll participants in July 1999 and completed the enrollment phase with 19,747 women in November 2004. We are currently monitoring participants in the trial's follow-up phase. As Dr. Lawrence Wickerham has noted, we will soon know the results from all of our efforts. Even though we will know which drug, tamoxifen or raloxifene, may be more beneficial to women at increased risk for breast cancer, this trial is still not over after the results are announced.

In late-April, your STAR site will contact you to discuss the results and to let you know what drug you have been taking in the study. However, if you have not completed your 5 years of protocol drug, please continue taking your pills until your STAR coordinator or physician directs you to do otherwise. If the STAR results show that there are only subtle differences between tamoxifen and raloxifene, you may not want to deviate from your assigned protocol drug. With that said, if there is evidence that either of these drugs

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19,747

October 31, 2004  
STAR enrollment ends surpassing our goal and 184,460 women had their breast cancer risk assessed. The participant follow-up phase continues.

19,000

June 23, 2004  
Shortly before the study's 5th birthday and a month earlier than expected, STAR reaches its enrollment goal.

16,359

June 30, 2003  
Happy 4th Birthday STAR!  
As of this date, 16,359 women enrolled in STAR and 158,896 women had their breast cancer risk assessed.

Due to the number and type of women participating in the study, the sample size was reduced from 22,000 to 19,000 women (May 2003).

13,647

June 30, 2002  
Happy 3rd Birthday STAR!  
As of this date, 13,647 women enrolled in STAR and 118,797 women had their breast cancer risk assessed.

10,473

June 30, 2001  
Happy 2nd Birthday STAR!  
As of this date, 10,473 women enrolled in STAR and 89,838 women had their breast cancer risk assessed.

6,136

June 30, 2000  
Happy 1st Birthday STAR!  
As of this date, 6,136 women enrolled in STAR and more than 47,000 women had their breast cancer risk assessed.

July 1, 1999  
Enrollment to STAR Began

## P-4: The Next Breast Cancer Prevention Trial

The NSABP is known to conduct clinical trials in a step-wise fashion. Results from completed trials guide the development of future studies. The Breast Cancer Prevention Trial (BCPT/P-1) found that tamoxifen reduced the incidence of breast cancer in women at increased risk for the disease by almost 50%. That finding led to the Study of Tamoxifen and Raloxifene (STAR/P-2). Our next breast cancer prevention trial protocol has been written and is awaiting review by the National Cancer Institute (NCI) once the STAR results are known.

P-4 will compare the more effective drug of STAR, either tamoxifen or raloxifene, to a new class of drug called an aromatase inhibitor (AI). Research done in women being treated for breast cancer has indicated that an AI may prevent the recurrence of breast cancer better than tamoxifen. Like STAR, P-4 will be available to

postmenopausal women who are at increased risk for breast cancer who never took a selective estrogen receptor modulator (SERM), like tamoxifen and raloxifene, or an AI for more than three months. If the study is approved by the government, it will involve 12,800 women in North America. We hope to launch it in the Fall of 2006. If you know any women who might be interested in P-4, you can refer them to this website, <http://www.breastcancerprevention.com>. There is a link on the website where women can sign-up to be notified of future trials, and they can also use the site to determine their risk of developing breast cancer.

*(Editor's Note: In case you are wondering why we jumped from P-2 to P-4, P-3 is a colon cancer prevention trial that is currently on hold.)*

## What Happens Now with Co-STAR?

Co-STAR is a substudy within the larger Study of Tamoxifen and Raloxifene (STAR) trial. It is designed to compare the effects of selective estrogen receptor modulators (SERMS), tamoxifen and raloxifene, on various cognitive functions like thinking and memory. As two of the most commonly prescribed SERMS, tamoxifen for the treatment and prevention of breast cancer and raloxifene for the treatment and prevention of osteoporosis, there is little information on this new class of drugs and cognitive aging.

By participating in Co-STAR, women taking these drugs are helping researchers obtain valuable information about cognitive functioning

that will contribute to the health care options of women for this generation and for generations to come.

Co-STAR has currently enrolled approximately 1,500 women into the study. With the unblinding of STAR set for April 2006, Co-STAR's enrollment will stop at that time. However, Co-STAR is in the process of revising the original study plans and may continue to provide follow-up testing of up to five tests. Even though you may have completed your 5 years of STAR study drug, you may still be eligible for additional Co-STAR testing.

**As always, we appreciate your continued support for Co-STAR.**

# Reflections

## From Inside a Clinical Trial

**Reflections...** was submitted by **Carol Lambertson, CRA, of Michigan**, a STAR participant and STAR Coordinator at the Munson Medical Center in Traverse City, Michigan (a member of the Grand Rapids CCOP). She has given permission for the NSABP to print this article in *Constellation*. The thoughts are her own and we thank her for sharing them with all of us.

## Fighting Cancer, From the Heart

Nearly every day Carol Lambertson thinks of something she wants to tell her mom and she reaches for the phone. Then she remembers...

On the day that Carol's mom died in February 2004, Jean Lambertson was riding in the back of an ambulance. Her son was following the ambulance in his car. Each time they came to a stoplight, Jean raised herself up off the gurney, stuck her thumbs in her ears, and wiggled her fingers at him. Despite the serious situation, he had to laugh.

By the time Carol drove to Lansing to meet them at the hospital, her 74 year-old mother was having an echocardiogram and was giving the technician a ration of good-natured trouble.

Jean Lambertson's family thought breast cancer would take her life. In the end, it was a heart attack.

Jean was diagnosed with breast cancer in October 2001. Ironically, Carol is a Cancer Research Associate for Munson Healthcare and has spent the past 10 years working in the area of cancer prevention. As her mother underwent surgery and radiation treatment, the work suddenly became quite personal.

In October 2003 the family learned that Jean's cancer had not responded to treatment, and had spread. "She died from a heart attack and we looked at that as a blessing," Carol said. "She had a very aggressive cancer and she would have been slated for a long, arduous ordeal. She was a trooper, but I'm grateful that she didn't have to go through that."

Jean Lambertson was the kind of woman who was always helping someone else, and never wanted anyone to lift a finger to help her. She took care of elderly friends, drove neighbors to appointments, cooked food for funerals, volunteered at church. "She did it so willingly and with a lot of good humor," Carol said.

### Good Memories

One Thanksgiving, all five of Jean's children traveled from around the country to show up for dinner. The next day, Jean, her daughters, daughters-in-law, and a granddaughter visited a wig shop to select a wig for her. "We spent an hour trying on wigs and taking pictures," Carol said.

"First we all did gray wigs. Then we all did the long Cher wigs. I put my leather jacket on my mom and perched her on a stool. We just had a blast. In all that process of fooling around, she was probably swearing to herself because she didn't want to wear a wig, but she tried to make everything lighthearted. For me, it will always be a good memory."

Last Christmas will be, as well. Carol and Jean went to North Carolina to spend the holiday with Carol's sister. The weather was perfect. Jean felt good all week. "That was the best week. We spent a lot of time baking cookies together. I have a picture of my mom wearing a Santa Claus hat making coffee cake."



Jean (front center) and Carol (right of front center) Lambertson try on wigs with a few friends.

Throughout her life, Jean Lambertson's typical response to any situation was, "Well, it could be worse." Carol has adopted her mother's attitude. "I'm a glass half-full kind of person," she said. "My mother never felt sorry for herself and she never wanted to be a burden to anyone. She even died on Feb. 29 and it occurred to me, 'Oh, she only wants us to remember it every four years'."

With her mother's diagnosis of breast cancer, Carol's own status of developing the disease changed to "high-risk." About 18 months ago Carol began taking part in a clinical drug study known as the STAR trial. The study is being conducted to compare the effectiveness of two drugs – tamoxifen and raloxifene – in preventing breast cancer.

### The Job Hits Home

Part of Carol's job has been to enroll women in the STAR trial. When it came time for her to decide whether she, herself, would participate, she fully understood what she'd been asking others to do.

"When I had to make that decision for myself, I found I was looking at it in a whole different light," she said. "My life is

pretty well fine. I didn't want to mess it up with side effects."

But she was also captivated by the fact that both drugs appear to dramatically reduce the incidence of breast cancer. A study published in 1998 showed that tamoxifen reduces breast cancer by about 50 percent. Raloxifene has been used to prevent and treat osteoporosis, but researchers noticed that women taking raloxifene were also less likely to develop breast cancer. The STAR trial is being done to determine which of the two drugs prevents breast cancer better and with fewer side effects.

"As I watched my mom undergoing treatment, I thought, 'Well, do I want to finish my career, retire, and then go through what my mom is going through, or do I want to do this now and not have to go through it?'"

Carol, and every other woman in the study, takes two pills each day. One contains either tamoxifen or a placebo, the other contains raloxifene or a placebo. Each participant receives a real drug in this blind study. Each woman is provided with medication for five years and has regular health checkups. Carol said she experienced the most common side effect – hot flashes – for about three months. Since then, she's not had any adverse reaction to the drug.

Researchers predict that women will know by 2006 which drug – tamoxifen or raloxifene – prevents breast cancer better and with fewer side effects. Fifty women from the Traverse City region are enrolled in the study through Munson Medical Center, Carol said. Many women were motivated by the fact that they have lost a mother, sister, daughter, or friend to breast cancer.

Enrollment for this trial is now closed, but women can still easily determine their risk factor by visiting [www.breastcancerprevention.com](http://www.breastcancerprevention.com) and answering a few questions. Carol urges women to consider being part of future research opportunities.

"Participating is easy and it's something you can do for yourself and for someone else."  
It's something Jean Lambertson would have done.

Every day, Carol still has the urge to pick up the phone and call her mom. "I just figure I have a direct line to her now."

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## What Happens Now?

shows a major benefit over the other then you will be directed accordingly by your STAR site personnel.

After 5 years your protocol therapy will stop, but your participation in the study continues. In the Spring 2004 issue of the *Constellation*, Dr. Wickerham addressed a variety of common questions, including:

- What will change when you stop your study drug?
- Why should you stop taking tamoxifen or raloxifene after 5 years?
- What should you do after you stop your protocol drug to reduce your chance of developing breast cancer? and,
- What can you do to prevent bone loss after you stop your study drug?

*If you missed this article or other Constellation articles, they are posted on the NSABP website (www.nsabp.pitt.edu) under "NSABP Newsletters."*

For the rest of this column, I want to discuss why it is important for STAR participants to continue their care in the study after the STAR results are announced.

- Your care remains the primary concern of your STAR physicians, nurses, and coordinators. The follow-up required in STAR is appropriate for women at increased risk for breast cancer.

- After 5 years of protocol drug, we will continue to ask you about your quality of life and your general health during the trial's follow-up phase for at least another 2 years and throughout your life.

- The NSABP has been conducting studies in the treatment of breast cancer for almost 50 years. In 1975, the NSABP began its B-06 study evaluating the use of lumpectomy in the surgical management of breast cancer. Over 2,100 women entered that study and many of them continue to be followed today.

- In 2002, the NSABP reported the 20-year results of the B-06 study and it was very important to assure both doctors and their patients that lumpectomy remains an effective treatment for breast cancer. Such reassuring long-term results were possible because the women in the study continued to participate long after they had completed treatment. Their willingness to continue to be followed has allowed hundreds of thousands of women to chose lumpectomy with the knowledge

- that it remains an effective option in the surgical management of breast cancer.

- We want you to participate in STAR for as long as you are willing to be followed. We recognize that this can be a challenge. We will make every effort to make this convenient whenever possible. **Our hope is that your long-term participation in STAR will also have a continued benefit for future generations of women.**

## Constellation

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