



NATIONAL SURGICAL ADJUVANT
BREAST AND BOWEL PROJECT

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For Immediate Release:

**Major Breast Cancer Prevention Trial Seeks Minority Women
During *National Minority Cancer Awareness Week***

Pittsburgh, PA—Researchers with the National Surgical Adjuvant Breast and Bowel Project (NSABP) are encouraging women from various racial and ethnic minority groups to consider joining a clinical trial during *National Minority Cancer Awareness Week*, April 16-22. The NSABP, with funding from the National Cancer Institute, conducts research studies to improve the prevention and treatment of breast cancer, as well as studies to improve the treatment of men and women with colorectal cancer. Many advancements in breast cancer prevention and treatment are due to results from NSABP studies.

“We are quite proud of the research we have done that has made a real difference in many individuals’ lives,” said Norman Wolmark, MD, NSABP chairman. “However, a major weakness in the present clinical trial system is that few women and men from racial and ethnic minority groups choose to participate in studies.”

A major NSABP trial underway is the Study of Tamoxifen and Raloxifene (STAR). STAR builds on the results of the NSABP’s Breast Cancer Prevention Trial (BCPT) which determined that the drug tamoxifen (Nolvadex®) could reduce the incidence of breast cancer by almost half in healthy women at high risk for the disease. Results from the BCPT paved the way for the 1998 Food and Drug Administration (FDA) approval of tamoxifen to reduce the incidence of breast cancer. STAR will compare the proven benefits of tamoxifen against the promising effects of raloxifene. Raloxifene (Evista®) has been approved by the U.S. FDA to prevent and treat osteoporosis in postmenopausal women. Early data from studies of raloxifene suggest that it may decrease breast cancer incidence as well. In STAR, 22,000 postmenopausal women who are at high risk for developing breast cancer will be enrolled over five years; as of March 31 of this year, 4,598 women had joined.

“Overall accrual to STAR is on track, and currently 4% of the women enrolled in STAR are from a racial or ethnic minority group,” says Wortia McCaskill-Stevens, MD, NCI program director for

STAR, although 12% of the women whose breast cancer risk has been evaluated represent a minority population.”

The NSABP has a special effort underway to educate minority women not only about STAR but also about breast cancer. SCOPE, the STAR Community Outreach Program for Education, seeks to address the myths that abound in the minority community about breast cancer; about who is at risk for the disease; and about why more minority women need to participate in clinical trials. Community outreach coordinators (COCs) now involved in SCOPE represent women from the African-American, Native American, and Hispanic communities in major cities in North America such as Philadelphia, Penn; Dallas Tex; Chicago, Ill; Tulsa, Okla; Houston, Tex; Phoenix, Ariz; Greenville, S Car; Washington, DC; and Winston-Salem, N Car. Efforts are underway to expand this program to the Asian-American community and other cities.

“The activities undertaken by each COC depend on the needs of the community. The COC who resides in a particular city is skilled in identifying not only community needs but also where minority women get their health information, and this varies,” according to Lora Ann Bray, community outreach coordinator for the NSABP. “Some COCs may provide health education in beauty salons, others may travel to businesses that employ minority women. The novelty of this program is that each COC has the ability to tailor its program to its own community and promote good breast health within it.”

Bertie Ford, RN, MS, OCN, the chairman of the NSABP’s Minority Representation Committee, states, “If we want answers about health problems that pertain to African-American women, then we must get involved in research studies. Much of the research done on women’s health problems has not involved many black women. Researchers are forced to assume that findings from those studies apply to all populations of women. I encourage all minority women to take part in clinical trials so that we can discover whether these assumptions are true.”

Women who participate in STAR must be postmenopausal, at least age 35, and have an increased risk of breast cancer as determined by their age, family history of breast cancer, personal medical history, age at first menstrual period, and age at first live birth. Once a woman chooses to participate, she will be randomly assigned to receive either 20 mg tamoxifen or 60 mg raloxifene daily for five years and will have regular follow-up examinations, including mammograms and gynecologic exams.

The maker of tamoxifen, AstraZeneca Pharmaceuticals, Wilmington, Del. and the maker of raloxifene, Eli Lilly and Company, Indianapolis, Ind., are providing their drugs for the trial without charge.

Over 500 centers across the United States, Puerto Rico, and Canada are participating in STAR, making the trial accessible to most women in those countries. The exams required in STAR are customary for women at high risk of developing breast cancer and are charged to a woman’s insurance. However, researchers state that the lack of health insurance should not deter a woman from joining the trial.

“Women who truly cannot afford the exams required to enter and stay in STAR may be eligible to take part in a program that may offset these expenses,” according to D. Lawrence Wickerham, MD, NSABP associate chairman and protocol officer.

For more information about clinical trials or STAR and a list of participating centers:

- In the United States (including Puerto Rico), call the National Cancer Institute’s Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) for information in English or Spanish. The number for callers with TTY equipment is 1-800-332-8615.
- In Canada, call the Canadian Cancer Society’s Cancer information Service at 1-888-939-3333 for information in English or French.
- Visit the NSABP’s Web site at <http://www.nsabp.pitt.edu> or NCI’s clinical trials Web site at <http://cancertrials.nci.nih.gov>

The NSABP, a non-profit, clinical trials cooperative group is supported primarily by grants from the NCI. For more than 40 years, the NSABP has successfully conducted large-scale, randomized clinical trials in colorectal and breast cancer that have altered and improved the standard of care for men and women with these diseases.

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