

# For Nearly 50 Years the NSABP has Been Leading the Way in Breast and Colorectal Cancer Research

1958

**1958** • The first patient was enrolled in the first randomized clinical trial undertaken by 23 researchers from participating sites throughout the United States. The results of the study provided the first evidence that the use of chemotherapy could significantly decrease early recurrence rates in some patients.



1967

Dr. Bernard Fisher was appointed the chairman of the Surgical Adjuvant Chemotherapy Breast Project. Dr. Fisher moved the Operations and Biostatistical centers to Pittsburgh, Pennsylvania.

1967

1971

Up until this time, physicians thought that breast cancer was a local disease that could only be treated with the complete removal of the breast, chest wall muscle, and underarm lymph nodes (radical mastectomy). Protocol B-04 was one of the first studies that indicated that the total mastectomy was just as effective as the more extensive operation. This landmark study gave way to future breast-conserving procedures.



1976

Protocol B-06, based on the results of Protocol B-04, showed that removing just the tumor and the underarm lymph nodes plus adding radiation therapy was just as effective as a mastectomy, but was far less disfiguring.

1977

1977

Protocols C-01 and R-01 were launched as the NSABP's first colorectal cancer treatment trials. C-01 evaluated postoperative immunotherapy and postoperative systemic chemotherapy in the management of resectable colon cancer. R-01 evaluated postoperative radiation and postoperative systemic chemotherapy in the management of resectable rectal carcinoma.

1982

1982

Protocol B-14 was one of the first studies that evaluated tamoxifen therapy in women whose tumors had not yet spread to the underarm lymph nodes and were estrogen-receptor positive (ER+). Results showed that women in the tamoxifen group had fewer recurrences of cancer and improved survival compared to the women who received placebo. This study also determined that there was no additional advantage for continuing tamoxifen therapy for more than 5 years.

1988

1988

Protocol B-18 demonstrated that therapy prior to surgery reduced the size of breast tumors in 80% of the patients, decreased the spread of the tumor to the lymph nodes and increased the number of women able to undergo lumpectomy.



1989

1989

Protocol C-04 assessed 2,151 patients who underwent a "curative" resection of a Duke's B or C carcinoma of the colon and demonstrated that the use of adjuvant 5-FU+ leucovorin is an acceptable therapeutic standard for such patients.

1991

1991

Findings for Protocol B-24 showed that tamoxifen treated women with ductal carcinoma in situ (DCIS) had fewer invasive and non-invasive breast cancers at five years than the women on placebo. The risk of breast cancer recurrence in the same breast as well as in the opposite, tumor-free breast was also found to be lower in the tamoxifen group. The study concluded that the combination of lumpectomy, radiation therapy, and tamoxifen was effective in the prevention of invasive cancer.



1994

1994

Dr. Norman Wolmark was named the new NSABP chairman. An established cancer researcher, he has been devoted to the evolution of large, randomized clinical trials to ascertain the best strategies for the treatment and prevention of breast and colorectal cancers.



1998

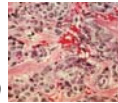
1998

The NSABP's first Breast Cancer Prevention Trial, or Protocol P-1, compared tamoxifen against placebo in 13,388 women at increased risk for developing breast cancer. Results from P-1 showed that tamoxifen could reduce the occurrence of breast cancer by 49% making it effective in significantly reducing the incidence of both invasive and non-invasive breast tumors in women at increased risk for the disease.

1999

1999

Protocol B-32 was designed to evaluate the removal of one or a few lymph nodes, the sentinel node(s), to ultimately determine if limited node removal provides the same detection and prognosis as the standard axillary dissection to control the further spread of cancer. In February 2004, this study completed accrual and a final analysis is pending.



2000

2000

Protocol C-07 opened and completed its accrual goal by early 2002. In May 2005, the NSABP announced its findings at an international meeting. The study showed that combining oxaliplatin with conventional treatment of 5-FU plus leucovorin significantly improved disease-free survival in patients with stage II or III colon cancer.

2000

Protocol B-31 opened and the study closed to accrual early in April 2005 due to positive results of a joint analysis with NCCTG N9831. Patients in both clinical trials who received trastuzumab (Herceptin®) with standard combination chemotherapy had a 52% decrease in disease recurrence compared to patients treated with chemotherapy alone.

2004

2004

The NSABP, in collaboration with Genomic Health, Inc., announced positive results of a new study using tissue from the NSABP Tissue Bank. The study demonstrated that the Oncotype DX™ 21-gene panel that quantifies the likelihood of breast cancer recurrence for a large portion of early stage breast cancer patients, can also predict the magnitude of chemotherapy benefit in these patients.

2006

2006

The NSABP announced the initial results of its second breast cancer prevention trial, the Study of Tamoxifen and Raloxifene (STAR). STAR enrolled 19,747 postmenopausal women at increased risk for developing breast cancer and showed that raloxifene was just as effective as tamoxifen in reducing their risk of developing invasive breast cancer by about 50 percent.



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