

SETTING OF PROSPECTIVE TRIALS: NSABP ORGANIZATION

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“Professionalism requires a commitment to the advancement of scientifically sound medical knowledge. One way to fulfill this obligation is through participation in clinical trials.”

The practice of medicine today is driven by evidence: data derived from published, prospective, randomized, and controlled clinical trials. As increasing demands on new drugs, devices, and treatments today, requires many clinical trials to evaluate them. Randomized clinical trials are the backbone of today's "evidence-based medicine" Many areas of medicine have seen a dramatic increase in clinical trials and landmark trials, such as the NSABP trials, have resulted in major changes in medical practice. An investigational therapy (intervention) is assigned at random to a participant, with either an alternative standard therapy or placebo assigned to other participants as controls in prospective, randomized clinical studies. The randomization process avoids bias in selecting treatments, which can confound the trial. In trials in which treatments are randomized, baseline characteristics of the study arms are usually comparable, and when the results between the groups are compared, differences in outcome cannot be confused by bias in selecting treatments or by baseline differences between the groups. Clinical trials follow strict scientific guidelines; every trial has a chief investigator who prepares a study action plan (protocol). Every research center that takes part in the trial uses the same protocol. Every study center has an Institutional Review Board that oversees clinical research in the health-care center. Each Phase III trial also has a data Safety and monitoring Committee that looks at the test results, monitors the safety of the participants and decides whether the study should go forward as originally planned. Despite the commonly held opinion by payers that it is more expensive to treat cancer patients in clinical trials, a study shows that it does not cost more and may actually cost less.

The National Surgical Adjuvant Breast and Bowel Project (NSABP) is a clinical trials cooperative group supported by the National

Cancer Institute (NCI). NSABP has a more than 40-year history of designing and conducting clinical trials that have changed the way breast cancer is treated, and, more recently, prevented. It was the NSABP's breast cancer studies that led to the establishment of lumpectomy plus radiation over radical mastectomy as the standard surgical treatment for breast cancer. NSABP was also the first to demonstrate that adjuvant therapy could alter the natural history of breast cancer, increasing survival rates, and the first to demonstrate on a large scale the preventive effects of the drug tamoxifen in breast cancer. Since its beginning the NSABP has enrolled more than 100,000 women and men in clinical trials in breast and colorectal cancer. NSABP has research sites at nearly 1000 major medical centers, university hospitals, large oncology practice groups, and health maintenance organizations in the United States, Canada, Puerto Rico, and Australia. At those sites and their satellites, more than 5000 physicians, nurses, and other medical professionals conduct NSABP treatment and prevention trials. Their presence at local hospitals and medical facilities means that state-of-the-art clinical trials can be provided to patients near their homes.

The NSABP was one of the first organizations to undertake large-scale studies in the prevention of breast cancer, and the Breast Cancer Prevention Trial (BCPT), which included more than 13,000 women at increased risk for breast cancer, demonstrated the value of the drug tamoxifen in reducing the incidence of the disease in this population. A second prevention trial, currently underway, the Study of Tamoxifen and Raloxifene (STAR), compares the effect of these two drugs in reducing the incidence of breast cancer. The Office of the Chairman and the NSABP Operations Center are located on the campus of Allegheny General Hospital, and the group's Biostatistical Center is at the University of Pittsburgh. In addition to funding from the NCI, which the NSABP has received since it began, the NSABP also receives support from other sources for ancillary studies, training, and educational programs